



CONTINUOUS GLUCOSE
MONITORING SYSTEM

USER'S GUIDE





**CONTINUOUS GLUCOSE
MONITORING SYSTEM**



IMPORTANT CONTACTS AND NUMBERS

Dexcom Website:	www.dexcom.com
Your Transmitter ID:	
Your Receiver ID:	
Your Healthcare Professional:	
Nearest Hospital:	
Other Notes:	

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DEXCOM G4 PLATINUM CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM



Dexcom G4 PLATINUM Receiver



Dexcom G4 PLATINUM Transmitter



Dexcom G4 PLATINUM Sensor

SYSTEM CONTENTS:

Reorder only the Dexcom G4 PLATINUM System components listed below:

- sensor
- transmitter
- receiver
- receiver USB charging/download cable
- charger - MT21255
- adapter plugs - MT21561
- receiver case
- user's guide
- quick start guide
- tutorial disc
- Dexcom Studio software (optional and available in select countries – check with your local distributor)

HELPFUL HINT:

Sensors are sold separately. Commercially distributed blood glucose (BG) meter required for use. Make sure to use the correct version of Dexcom Studio with your system. The sensor works with the Dexcom G4 PLATINUM family of products. The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver.

INTRODUCTION

When you use the system, you will see continuous sensor glucose readings updated every 5 minutes for up to 7 days. These readings will help you detect trends and patterns in your glucose levels.

The system includes the sensor, the transmitter, and the receiver. The sensor is a disposable unit that you insert under your skin to continuously monitor your glucose levels for up to 7 days. The transmitter is a reusable device that wirelessly sends your sensor-measured glucose information to your receiver. The receiver is a hand-held device that receives and displays your glucose information.

This user's guide describes how to use your system.

Please review this user's guide.

HELPFUL HINT:

Dexcom has developed an interactive, self-guided training tutorial for the Dexcom G4 PLATINUM CGM System based on well-established adult-learning principles. Some people have found this to be an effective method of product training. Please review the tutorial on the disc and discuss with your healthcare professional if the Dexcom G4 PLATINUM training tutorial is an appropriate training option for you.

INDICATIONS FOR USE

The Dexcom G4 PLATINUM Continuous Glucose Monitoring System is a glucose-monitoring device indicated for detecting trends and tracking patterns in persons (**age 2 and older**) with diabetes. The system is intended for use by patients at home and in healthcare facilities.

The Dexcom G4 PLATINUM System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM System results should be based on the trends and patterns seen with several sequential readings over time.

IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

CONTRAINDICATIONS

- The blood glucose value from your blood glucose meter should be used for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver must be removed prior to Magnetic Resonance Imaging (MRI), CT scan, or diathermy treatment. The Dexcom G4 PLATINUM System has not been tested during MRI or CT scans or with diathermy treatment, and it is unknown if there are safety or performance issues.
- Taking acetaminophen (paracetamol) containing products (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen (paracetamol) active in your body.

WARNINGS

- Do not use the Dexcom G4 PLATINUM CGM System until after you have been trained or viewed the training materials included with your CGM system.
- The blood glucose value from your blood glucose meter should be used for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter. Blood glucose values may differ from sensor glucose readings. The direction, rate of glucose change, and trend graph on your Dexcom G4 PLATINUM System provide additional information to help with your diabetes management decisions.
- Symptoms of high and low glucose should not be ignored. If your sensor glucose readings do not fit with your symptoms, you should measure your blood glucose with a blood glucose meter.
- In a pediatric clinical study, larger differences were observed between this CGM device and actual blood glucose values compared to those differences observed in the adult clinical study. Use your blood glucose meter for treatment decisions.
- In a pediatric clinical study a significant number of low glucose events were not detected by CGM. Do not rely solely on CGM alerts to detect low glucose.
- Your sensor glucose readings may be inaccurate if you calibrate less than every 12 hours.
- Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to your local distributor.
- The Dexcom G4 PLATINUM System **is not approved for use** in pregnant women or persons on dialysis.
- Sensor placement **is not approved** for sites other than under the skin of the belly (abdomen) or, in the case of patients between the ages of 2 and 17, the belly or upper buttocks.
- If your transmitter or receiver case is damaged/cracked, do not use them, as this could create an electrical safety hazard or malfunction.
- The sensor and transmitter include small parts that may pose a choking hazard. Keep the transmitter kit box away from young children; it contains a magnet that should not be swallowed.

PRECAUTIONS

- Before opening the sensor package, wash your hands with soap and water and dry them to avoid contamination.
- Before inserting the sensor, always clean the skin at the sensor insertion location with a topical antimicrobial solution, such as isopropyl alcohol. This may help prevent infection. Do not apply the sensor until the cleaned area is dry so that it will stick better.
- Change the site where you place your sensor with each insertion to allow your skin to heal.
- Avoid areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation, as these are not ideal sites to measure glucose.
- Avoid injecting insulin or placing an insulin pump infusion set within 7.62 cm of the sensor in case the insulin affects the sensor glucose readings.
- The sensor is sterile in its unopened, undamaged package. Do not use any sensor if its sterile package has been previously damaged or opened.
- To calibrate the system, you must enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes ago could result in inaccurate sensor glucose readings.
- The transmission range from the transmitter to the receiver is up to 6 meters without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, water bed, etc.
- Sensors should be stored at temperatures between 2° C - 25° C for the length of the shelf life. You may store your sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.
- Keep the USB port cover on the receiver closed whenever the USB cable is not attached. The receiver may malfunction if water gets into the USB port.

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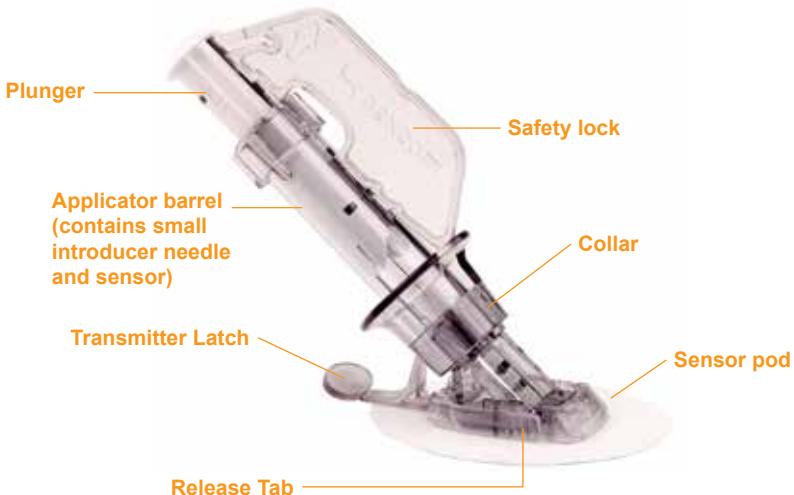
chapter one

THE DEXCOM G4 PLATINUM SYSTEM BASICS

1.1 SENSOR OVERVIEW

The sensor is placed under the skin of your belly and continuously measures your glucose levels.

The sensor and transmitter (once snapped in place) remain on your skin for the entire sensor session, up to 7 days.



1.2 TRANSMITTER OVERVIEW

The transmitter wirelessly sends your glucose information to the receiver. The transmitter and sensor are water resistant when properly connected. Do not throw away your transmitter. It is reusable.

The transmission range from the transmitter to the receiver is up to 6 meters without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, water bed, etc.

The transmitter battery will last at least 6 months. Once you see the transmitter low battery screen shown on the right, replace the transmitter as soon as possible. Your transmitter battery may drain as quickly as one week after this alert appears.

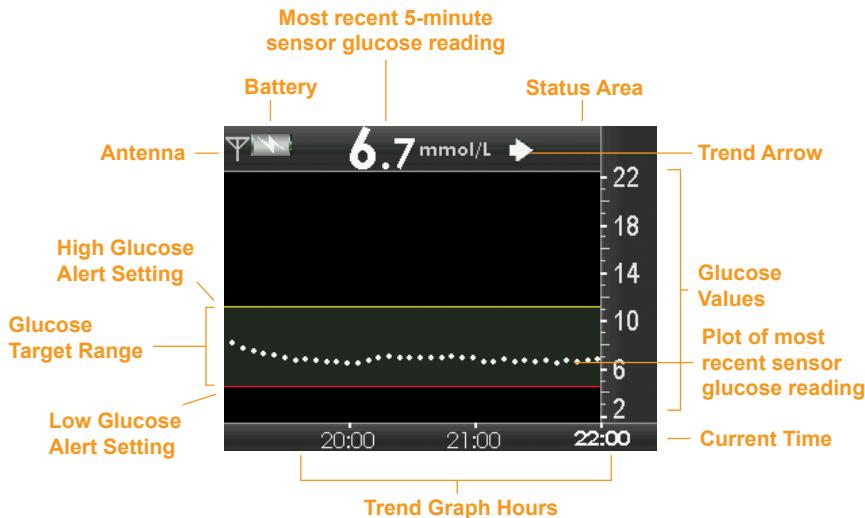


1.3 RECEIVER OVERVIEW

The receiver is a small hand-held device that shows your sensor glucose readings, direction and rate of change arrow and trend graph. The international standard unit of measurement used for glucose testing systems (i.e., blood glucose meters) is mmol/L (millimoles per liter). The transmission range from the transmitter to the receiver is up to 6 meters.

Your receiver is rated IP22, which means that it offers some protection from rain drops. Do not spill fluids on the receiver or drop the receiver into fluids. Keep the micro USB port cover closed to help prevent fluid and dust from getting inside the receiver.

Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, water bed, etc.



EXAMPLE: 3-Hour Trend Graph Screen

There are five receiver buttons to move you through the display screens that control setup and operation and allow you to change your receiver settings. The screens display sensor glucose readings, trend graphs and trend arrows.

Your receiver and transmitter are wirelessly paired together to communicate securely and only with each other.

You will need a commercially available blood glucose meter to use with your system.



1.4 CHARGING YOUR RECEIVER BATTERY

The receiver battery is rechargeable. The rechargeable battery will typically last about 3 days before you need to charge it with the charging cable provided. Your battery life depends on how often you interact with your receiver. The receiver will alert you when the battery charge is low.

The receiver battery may be charged using one of the following options:

- an AC power outlet
- a personal computer with Windows operating system (to charge your receiver from your PC, Dexcom Studio must be installed. For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom Studio Software User's Guide.)

It takes about 3 hours to fully charge an empty battery with the wall charger, and about 5 hours when the receiver is connected to a computer.

You can charge your receiver at any time and the battery does not need to be drained in order to fully charge the battery.



Low battery prompt

HELPFUL HINT:

- When the receiver is used in a healthcare facility, charging must take place away from the patient.

1.4.1 CHARGING YOUR RECEIVER BATTERY FROM AN AC POWER OUTLET

The AC power adapter comes with interchangeable plugs.



Install the appropriate plug for your wall outlet style by sliding the plug down onto the adapter until it snaps into place.

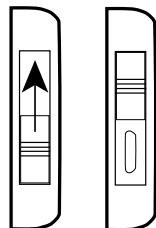


To remove the plug from the AC power adapter place both thumbs on the bottom of the plug and push up until the plug pops out of the adapter.



To recharge your battery, follow the instructions below:

1. Plug the included USB cable into the AC power adapter.
2. Plug the AC power adapter into an AC power outlet.
3. Slide open the USB port cover on the side of the receiver to access the port.
4. Plug the micro USB end of the cable into the receiver USB port.



Keep the USB port cover on the receiver closed whenever the USB cable is not attached.

HELPFUL HINT:

- Press down firmly with your thumb when sliding open the USB port cover.

5. The battery charging screen will appear on the receiver.



6. After a few seconds the trend graph will reappear with the battery charging symbol (■) shown in the upper left corner.



1.4.2 CHARGING YOUR RECEIVER BATTERY FROM A WINDOWS COMPATIBLE COMPUTER

The Dexcom Studio software must be installed to charge your receiver from a computer.

1. Plug the included USB cable into your computer.
2. Plug other end of the USB cable into the receiver.
3. The battery charging screen will appear on the receiver.



4. After a few seconds the trend graph will reappear with the battery charging symbol shown in the upper left corner.

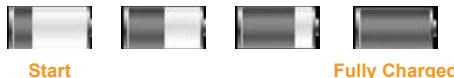


HELPFUL HINT:

- Charge only from a USB port on your computer or the AC power adapter. Do not use an external USB hub. An external USB hub may not provide enough power to charge the receiver.

1.4.3 KNOWING YOUR RECEIVER IS CHARGED

1. As the battery charges, the battery symbol will begin to fill in. The battery is fully charged when battery symbol is completely shaded.



2. After the charge is complete, remove the cable from the receiver and the wall outlet or computer USB port.

HEI PEJU HINTS:

- Charge your receiver battery before each sensor insertion. Periodically check your battery level to make sure it has enough charge.
- If your battery drains it will retain the time and date for 3 days without being charged. After 3 days you will be prompted to reset your receiver time and date (see Chapter 2, Section 2.2, The Settings Menu).
- Only use the Dexcom battery charger provided in the receiver kit. Do not use any other battery charger.

More information on main menu options can be found in the sections listed below:

Menu	Purpose	User's Guide Reference
Trend Graph	To display the trend graphs. • The 3-hour trend graph is the default screen displayed whenever you turn the receiver on.	Chapter 5
Start Sensor	To start a new sensor session. • This option only appears if a transmitter ID has been entered and you are not in the middle of a sensor session.	Chapter 3
Enter BG	To enter your blood glucose values for calibration.	Chapter 4
Profiles	Profiles allow you to customize the sound pattern and volume level of alerts and alarms to meet your needs.	Chapter 6
Events	To enter personal information about meals, insulin, exercise, and health status.	Chapter 7
Alerts, High/Low	To change the settings for notifications of high and low alerts from your receiver.	Chapter 6
Settings	To change the time, date and transmitter ID, to look up your Dexcom G4 PLATINUM System hardware and software version numbers, to view transmitter battery status, last calibration value, sensor insertion time.	Chapter 2
Shutdown	To temporarily turn off all communications between your sensor, transmitter and receiver during an active sensor session. You will not receive sensor glucose readings, and it will not extend the life of your sensor.	Chapter 3
Stop Sensor	To end a sensor session early. • This option only appears when you are in the middle of a sensor session. You will not receive sensor glucose readings. It will not extend the life of your sensor.	Chapter 9

See Appendix I, Receiver Alerts, Alarm and Prompts, for a list of screens that may appear on the receiver during use.



chapter two

DEXCOM G4 PLATINUM SYSTEM SETUP

This chapter will help you when you first set up your Dexcom G4 PLATINUM Continuous Glucose Monitoring System. Read this chapter before you start.

2.1 THE SETUP WIZARD

1. Before setting up the receiver remove the transmitter from its packaging. It takes 10 minutes for the transmitter to turn on after it is removed from its packaging.
2. Make sure your receiver is fully charged (see Chapter 1, Section 1.4, Charging Your Receiver Battery).
3. Turn your receiver on by pressing the **SELECT** button on the receiver. When you turn the receiver on for the first time, the Setup Wizard will help you get started by prompting you to enter the following setup information:

- a. Select your language.

- Press the **UP** or **DOWN** button to choose your desired language.
- Press the **SELECT** button to set the highlighted language.



- b. Set the time format.

- Time formats available are either 24 Hour or AM/PM (12-hour) settings.
- Press the **UP** and **DOWN** button to choose your desired time format.
- Press the **SELECT** button to confirm changes to time format.



2

c. Set the time and date. The date format is YYYY/MM/DD.

- Press the **UP** or **DOWN** button to enter the current date and time.
- Press the **RIGHT** button to move to the next section.
- Press the **SELECT** button to confirm changes to time and date.



d. Enter your transmitter ID.

- Press the **UP** or **DOWN** button to enter your transmitter ID.
- Press the **SELECT** button to confirm entry of transmitter ID.



Your transmitter ID is unique and contains a code with 5 numbers and/or letters and can be found in the following locations:

- On the outside of the transmitter box label.
- On the bottom of the transmitter.

HELPFUL HINTS:

- Write your transmitter ID number down in the Important Contacts and Numbers list on page 4.
- If you need to change the language, time format, time, date or transmitter ID after you have completed the Setup Wizard see Section 2.2, The Settings Menu.

e. Set your low and high glucose alert values. Your low and high glucose alerts are pre-set to 4.4 mmol/L and 11.1 mmol/L, but can be changed to meet your needs.



- Press the **UP** or **DOWN** button to select your desired alert value. Changes can be made in increments of 0.1 mmol/L.
- Press the **SELECT** button to confirm your preferred alert value.

The Setup Wizard is now complete. To begin using your Dexcom G4 PLATINUM CGM System you will need to insert a sensor (see Chapter 3, Inserting a Sensor and Starting a Sensor Session).

HELPFUL HINTS:

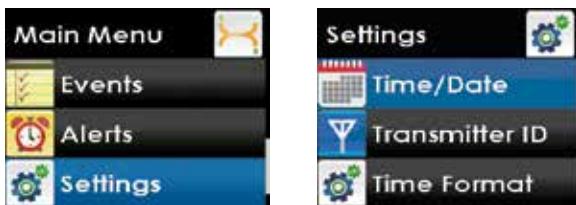
- You can also change your alert values in the alerts menu.
- The unit of measure (mmol/L) is not adjustable.

2.2 THE SETTINGS MENU

The settings menu shows you how to change the time, date or transmitter ID after you have already completed the Setup Wizard.

2.2.1 GETTING TO THE SETTINGS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will appear.
2. Press the **SELECT** button to display the Main Menu.
3. From the main menu, press the **UP** or **DOWN** button to scroll to “Settings” and press the **SELECT** button. The settings menu will appear.



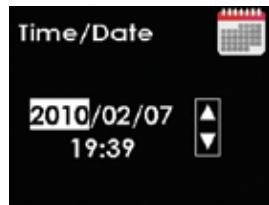
2.2.2 SETTING YOUR RECEIVER TIME AND DATE

To set the time and date follow the steps below.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Time/Date” and press the **SELECT** button.



2. Press the **RIGHT** button to highlight each value in the date and time. Then, press the **UP** or **DOWN** button to make any adjustments and then press the **RIGHT** button to move to the next value. The date format is YYYY/MM/DD. After choosing the time, press the **SELECT** button. You will return to the settings menu.



HELPFUL HINT:

- You might need to reset the receiver's time and date if the rechargeable battery is drained. If this happens, you will be alerted and automatically taken to the time/date setting screen.

2.2.3 ENTERING YOUR TRANSMITTER ID

Any time you switch to a new transmitter and/or receiver (as a replacement to the transmitter and/or receiver that came in your kit) you must enter the transmitter ID into your receiver. The transmitter ID is a series of 5 numbers and/or letters that can be found in the following locations:

- On the outside of the transmitter box label.
- On the bottom of the transmitter.

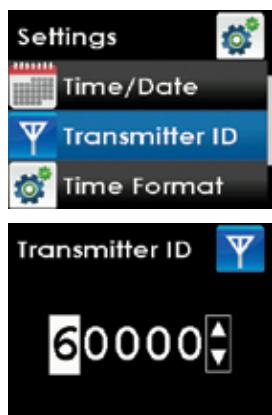
If you have difficulty locating your transmitter ID, please contact your local distributor.

HELPFUL HINT:

- You can only set your transmitter ID when you are not in a sensor session. During a sensor session, "Transmitter ID" will not appear as an option on the settings menu.

To enter the transmitter ID follow the steps below.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Transmitter ID" and press the **SELECT** button.
2. Starting with the first number or letter (do not enter "SN"):
 - a. Press the **UP** or **DOWN** button to display to the correct number or letter.
 - b. Then press the **RIGHT** button to move to the next value and repeat step a. Continue repeating steps a and b until you have the transmitter ID displayed.
 - c. After entering the fifth number or letter, press the **SELECT** button. You will return to the settings menu.



2.2.4 SETTING YOUR RECEIVER TIME FORMAT

To set your receiver time format (24-hour or AM/PM) follow the steps below.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Time Format” and press the **SELECT** button.



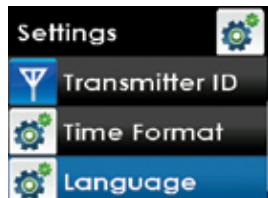
2. Press the **UP** or **DOWN** button to scroll and highlight your desired time format.
3. Press the **SELECT** button to set the highlighted time format. You will return to the settings menu.



2.2.5 SELECTING YOUR RECEIVER LANGUAGE

To select your receiver language follow the steps below.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Language” and press the **SELECT** button.



2. Press the **UP** or **DOWN** button to scroll and highlight your desired language.
3. Press the **SELECT** button to set the highlighted language. You will return to the settings menu.



2.3 CHECKING INFORMATION ABOUT YOUR DEXCOM G4 PLATINUM SYSTEM

You can check your receiver for information about your CGM at any time.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to “Device Info” and press the **SELECT** button.



2. Information about your sensor session and system will appear. Scroll down to see all of the Device Info:

- Insertion Time
- Last Calibration
- Transmitter Battery
- Transmitter ID
- Serial Number
- Part Number
- Part Revision
- Software Number
- Software Revision



3. Press the **LEFT** button to return to the Settings menu.

2.4 TRANSMITTER AND RECEIVER COMMUNICATION



The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver must be removed prior to Magnetic Resonance Imaging (MRI), CT scan, or diathermy treatment. The Dexcom G4 PLATINUM System has not been tested during MRI, CT scans or with diathermy treatment, and it is unknown if there are safety or performance issues.



The transmission range from the transmitter to the receiver is up to 6 meters without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, water bed, etc.

HELPFUL HINT:

- The transmitter and receiver may lose communication at the following times:
 - When they are near metallic objects.
 - When you are using an electric blanket.

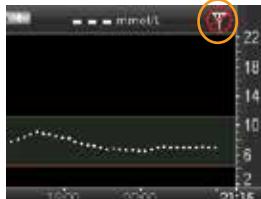
Once you are in a sensor session, you can check that the receiver and transmitter are communicating. View the trend graph screen by pressing the **SELECT**, **LEFT** or **RIGHT** button to see the trend graph.



This antenna symbol shows that the transmitter and receiver are communicating.



This out of range symbol shows the transmitter and receiver are not communicating.



chapter three

INSERTING A SENSOR AND STARTING A SENSOR SESSION

To use your Dexcom G4 PLATINUM Continuous Glucose Monitoring System you will need a sensor, a transmitter, and a receiver. You will also need a blood glucose meter and test strips for calibration. Once inserted and calibrated, the sensor will continuously measure and display your sensor glucose readings for up to 7 days. The following sections will show you how to insert the sensor and start a new continuous glucose monitoring session.

Please review the tutorial on the disc in your kit. The tutorial is also available online at www.dexcom.com.



Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to your local distributor.

For patients undergoing an MRI with a retained wire broken off from a Dexcom G4 PLATINUM Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant movement or heating of the wire and imaging artifacts were limited to the area around the wire.

3.1 BEFORE YOU START

- Make sure you charge your receiver completely. See Chapter 1, Section 1.4, Charging Your Receiver Battery.
- Check that the date and time are correct on the receiver.
- Make sure the correct transmitter ID has been entered into your receiver (see Chapter 2, Section 2.2, The Settings Menu).
- Check the Use by Date on the sensor. The Use by Date format is YYYY-MM-DD. Sensors must be inserted on or before the end of the calendar day printed on the sensor package label.
- Make sure you are using your blood glucose meter per the manufacturer's instructions to ensure you are getting accurate blood glucose values for calibration.

- ☐ Clean the bottom of the transmitter with a slightly damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.
- ☐ Make sure your blood glucose meter and receiver date and time match.



Sensors should be stored at temperatures between 2° C - 25° C. You may store your sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.

REVIEW THE SENSOR APPLICATOR

Review the sensor applicator picture below before using a new sensor.



3.2 REMOVING THE SENSOR FROM ITS PACKAGING



The sensor is sterile in its unopened, undamaged package. Do not use any sensor if its sterile package has been previously damaged or opened.

- Wash your hands thoroughly and dry them.
- Carefully remove the sensor from its packaging. Look closely at the sensor to make sure it is not damaged.
- The applicator is a single use, disposable unit. The safety lock prevents you from accidentally releasing the needle before you are ready. The applicator and sensor design prevents reuse.

3.3 CHOOSING AN INSERTION SITE



Change the site where you place your sensor with each insertion to allow your skin to heal.

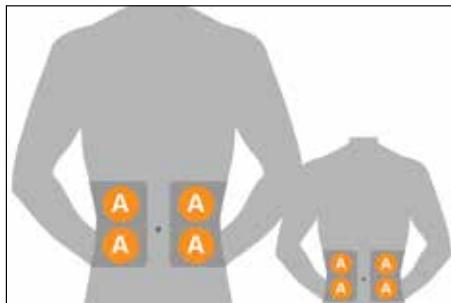
Avoid areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose.

Avoid injecting insulin or placing an insulin pump infusion set within 7.62 cm of the sensor in case the insulin affects the sensor glucose readings.

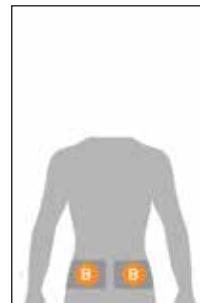
Reviewing the tutorial disc would be helpful to learn how to insert your sensor. Choose a site to place the sensor.

- **Adults age 18 or older:** insert in the belly (front of body, option A).
- **Children and adolescents between 2 and 17 years old:** insert in the belly (front of body, option A) or the upper buttocks (back of body, option B).

No other sensor insertion sites have been tested.



**Front of body, sensor site option A
(ages 2 and older)**



**Back of body,
sensor site option B
(ages 2-17 only)**

The ideal sensor insertion site for you may be based on your body type, activity, sensitivities, and other personal traits. You can choose a site above or below your belt line. The best areas to insert your sensor are usually flat and “pinchable.” Avoid sensor insertion where something may rub or press against the sensor. For example, avoid sensor insertion along the waist band and seat belt strap, in or near the belly button, on the upper buttocks near the waist/belt or too low on the buttocks where you sit.

- Choose an area that is at least 7.62 cm from where you plan to inject insulin or from where your pump infusion site is located.
- Avoid using the same spot repeatedly for sensor insertion. Never use the same site for 2 sensor sessions in a row.
- You may need to shave the area where you plan to put the sensor so that the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the skin where you place the sensor.

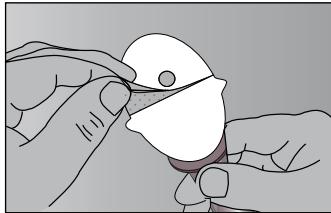
For more help on ideal sensor insertion sites for you, contact your health care provider.

3.4 PLACING THE SENSOR

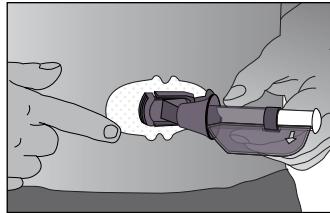
1. Clean the area first with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor.

NOTE: Skin preparation or adhesive products (Mastisol, SkinTac) are optional. If you use an optional skin preparation or adhesive product, place it on the skin in a “doughnut” shape where you will place the sensor adhesive patch. Insert the sensor through the clean skin at the center of the doughnut where it is free of skin preparation or adhesive products. Let dry (skin may feel tacky).

2. Using the white tabs on the adhesive backing, remove the adhesive backing from the sensor pod one half at a time. Hold the sensor by the applicator barrel and try not to touch the sticky adhesive patch.
3. Place the sensor flat on your selected area. Make sure the sensor is placed in the same direction shown in the picture below. You should not place the sensor pointing in the up or down direction.

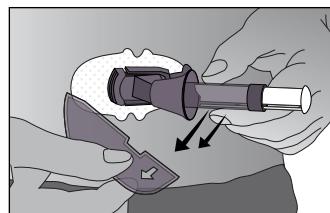
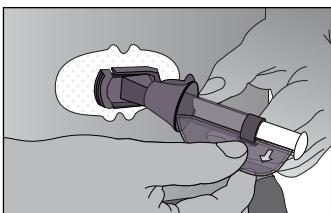


Remove the adhesive backing



Adhere the sensor on the skin

4. Press your finger firmly around the adhesive patch to make sure it is smooth.
5. Hold on to the applicator. Then pull the safety lock straight out away from the applicator, in the direction the arrows show in the following picture.



Remove the safety lock

HELPFUL HINT:

- The safety lock can be used later for transmitter removal. Keep this piece to help you remove the transmitter at the end of a continuous glucose monitoring session. When your glucose monitoring session is over, follow the steps in Chapter 8, Section 8.3, Transmitter Removal.

NOTE: Contact your health care provider for specific questions regarding the use of medical tape, barrier wipes and/or other adhesives as it relates to your use of Dexcom CGM.

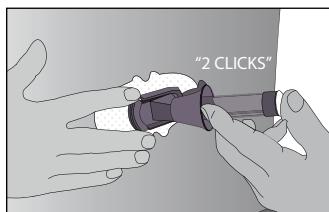
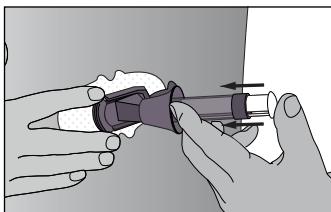
3.5 SENSOR INSERTION

Once you have placed the applicator on your skin and removed the safety lock, you are ready to insert the sensor. To insert your sensor follow these steps:

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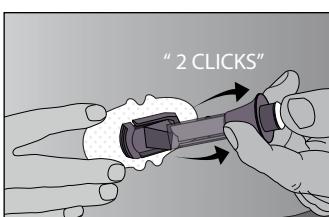
1. Using one hand, you may want to pinch up on the skin, at the edge of the white adhesive. Do not pinch up in the middle section of the plastic base. With your other hand, place two fingers above the collar on the applicator barrel so they are resting above the collar.
2. Place your thumb on the white plunger. Push the plunger down completely, making sure it is flush against the applicator barrel. You should hear 2 clicks. This action inserts the needle and sensor under your skin.

When you are pushing down on the plunger, do not pull back on the collar.



Push down the plunger – Insert the needle and sensor

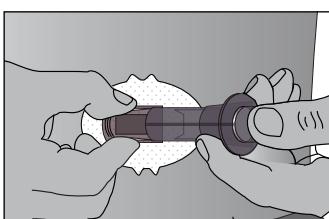
3. To remove the sensor introducer needle, keep pinching up on your skin with one hand. With your other hand, place two fingers under the collar. Keep your thumb lightly on top of the white plunger and pull the collar back towards your thumb until you hear 2 “clicks” or cannot pull back any more. This step leaves the sensor under your skin and removes the sensor introducer needle from your body.



Pull back the collar - Retract the Needle

4. To remove the applicator barrel, squeeze the ribbed release tabs on the sides of the sensor pod (when you squeeze the front part of the release tabs, the back part of the tabs will widen, allowing you to pull off the applicator barrel). After this step, only the sensor pod will be left on your body.

- Make sure the transmitter latch is down (against your body) to remove the applicator barrel.



Release the applicator barrel

- Be sure to squeeze in the center of the ribbed part of the release tabs.
- While squeezing the release tabs rock the applicator barrel forward and out away from the body.

If you have any problems with insertion, save the sensor and applicator and contact your local distributor.

3.6 TRANSMITTER ATTACHMENT

Once you have inserted your sensor, you will need to snap the transmitter into the sensor pod. Follow the steps below to attach your transmitter.

1. Clean and dry the bottom of the transmitter with a damp cloth or an alcohol wipe before every use. Be careful not to touch the metal circles on the bottom of the transmitter with your skin. For disinfection instructions refer to Chapter 10, Section 10.3, Cleaning and Disinfection. Be careful not to scratch the bottom of the transmitter as scratches may compromise the waterproof seal.
2. Place the transmitter in the sensor pod with the flat side facing down.



Install transmitter in sensor pod

3. With one hand, you may want to pinch up on your skin at the front edge of the white adhesive.
 - a. Place one finger on the transmitter to keep it in place while securing the transmitter into the sensor pod.
 - b. Pull the transmitter latch over the transmitter to snap the transmitter into place. The transmitter should lie flat in the sensor pod. You should hear 2 “clicks.” If you do not hear 2 “clicks,” the transmitter might not be fully snapped in place. You can release your pinch on the adhesive edge at this time.
- c. Make sure the transmitter is secure by sliding your first and second fingers under the sensor pod wings and press down on the transmitter with your thumb.



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4. Hold the transmitter in place with one hand. Using your other hand, remove the transmitter latch by holding the end of the latch and quickly twisting off the latch away from your body.



Remove transmitter latch

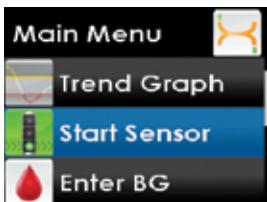
HELPFUL HINTS:

- Make sure you hear 2 clicks when you snap the transmitter in place (see Step 3). Failing to seat the transmitter completely may lead to a poor sensor connection and allow fluids to get under the transmitter. This can lead to inaccurate sensor glucose readings.
- **Do not remove the transmitter from the sensor pod while the pod is attached to your skin.**

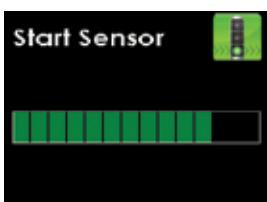
3.7 STARTING A SENSOR SESSION

Follow the steps below to tell the receiver that you have inserted a new sensor.

1. Press the **SELECT** button to turn the receiver on.
2. From any trend graph, press the **SELECT** button to display the main menu.
3. Press the **Up** or **DOWN** button to scroll until you highlight “Start Sensor.”



4. Press the **SELECT** button to confirm the start of a new sensor session. The start sensor processing screen will appear to let you know your sensor session has been activated and your 2-hour startup has begun.
5. Your receiver will then return to the 3-hour trend graph.



6. Check your receiver in approximately 10 minutes after starting your sensor session to make sure your receiver and transmitter are communicating. The antenna symbol  should appear in upper left corner of trend graph. If the out of range symbol  appears in the upper right corner of the trend graph, see Chapter 9, Section 9.9, Out of Range/No Antenna.



HELPFUL HINTS:

- The start sensor menu option will disappear from the main menu. The option will only appear again after an active sensor session ends. If you do not see the start sensor option on your menu screen, you can continue that session or stop the session (refer to Chapter 9, Section 9.6, Sensor Shut-off Troubleshooting).
- After starting a new sensor session, you will not receive sensor glucose readings or alerts until your 2-hour startup period has ended and you have completed your initial calibrations. See Chapter 4, Section 4.3, Startup Calibration.

3.8 SENSOR STARTUP PERIOD

The sensor needs a 2-hour startup period to adjust to being under the skin.

When you press the **SELECT** button during the startup period to turn the receiver display on, your trend graph will include a 2-hour countdown symbol  in the upper right hand corner.



Over time, the countdown symbol  will fill to indicate that you are getting closer to initial calibration time. See the pictures below for an example of what this looks like. During the countdown period, you will not get sensor glucose readings, alerts and alarms.



Throughout the 2-hour startup period if you see the out of range  symbol at the top of the screen review the following troubleshooting tips.

- Make sure your receiver and transmitter are within 6 meters of each other. Check in 10 minutes to see if the antenna symbol reappears in the upper left corner of the receiver screen.
- If the receiver and transmitter are still not communicating, check the device information screen to make sure the correct transmitter ID is entered into your receiver (see Chapter 2, Section 2.3, Checking Information About Your Receiver).
- If the correct transmitter ID has been entered into your receiver and the receiver and transmitter are still not communicating, then contact your local distributor.

At the end of the 2-hour startup period the receiver will let you know that it is time to calibrate your sensor. Chapter 4, Calibrating Your Dexcom G4 PLATINUM System, tells you how to calibrate your sensor.

3.9 TAPING THE SENSOR POD

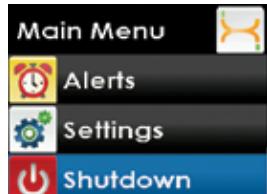
The sensor pod should stay securely attached to your skin using its own adhesive. But, if the patch is peeling up, you can use medical tape (such as Blenderm, Tegaderm, IV 3000, 3M tape) for extra support. If you use tape, only tape over the white adhesive patch on all sides for even support. Do not tape over the transmitter or any of the plastic parts of the sensor pod. Do not tape under the sensor pod or leave any substance on the skin where you insert the sensor.



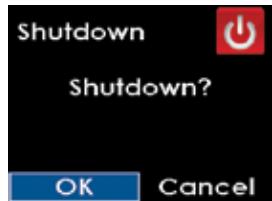
3.10 TEMPORARY RECEIVER SHUTDOWN

There may be times when you want to temporarily shut down your receiver. Shutdown will stop all communication between the transmitter and receiver, and will turn the receiver off. You will not receive sensor glucose readings or **any** alerts or alarms while the receiver is shut down, but your current sensor session will continue. Follow these steps to shut down your receiver:

1. From the main menu, scroll to and highlight “Shutdown.” Press the **SELECT** button.



2. Confirm that you want to shutdown your receiver.
 - a. If you want to shutdown, press the **LEFT** button to highlight “OK” and then press the **SELECT** button.
 - b. If you want to cancel the shutdown, press the **SELECT** button (with “Cancel” highlighted) to return to the main menu.



3. To turn the receiver back on and resume communication with the transmitter, press the **SELECT** button. It may take up to 20 seconds for the display to turn back on.

HELPFUL HINTS:

- Remember that your alerts and low glucose alarm will not work when the receiver is shut down.
- Shutting down the receiver does not extend the sensor life beyond 7 days. Your sensor session will stop 7 days after you started the sensor session.

3.11 THE DEXCOM G4 PLATINUM SYSTEM AND WATER

Your sensor is water resistant when showering, bathing, or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 2.44 meters for a maximum of 24 hours. The receiver is rain resistant, but you should try to keep it dry. Do not spill fluids on it or drop it into fluids. **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.** Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, water bed, etc.

HELPFUL HINT:

- If your receiver gets wet you need to make sure the speakers and vibrate mode are still working. You can do this by using the Try It option in the profiles menu. See Chapter 6, Section 6.3, Alert Profiles.

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chapter four

CALIBRATING YOUR
DEXCOM G4 PLATINUM SYSTEM

The Dexcom G4 PLATINUM System requires you to calibrate the sensor glucose readings to your blood glucose meter.



Taking acetaminophen (paracetamol) containing products (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen (paracetamol) active in your body.

4.1 CALIBRATION OVERVIEW

There are important times when you **must** calibrate:

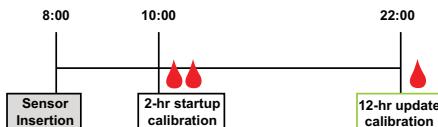
1. Initial startup: 2 hours after you insert your sensor
2. 12 hour update: every 12 hours after the initial startup calibration
3. More information needed or other reasons

When calibrating, you need to manually enter your blood glucose values into the receiver. You can use any commercially available blood glucose meter.

On the first day of your sensor session, you will need to enter 2 blood glucose values into your receiver as your 2 hour startup calibration. After your 2 hour startup calibration has been entered, you will need to enter 1 blood glucose value as your calibration at 12 hours after your startup calibration. From that point on you will need to enter 1 blood glucose value every 12 hours. The receiver will remind you when these calibrations are needed. You may also be prompted to enter additional blood glucose values as needed. An example of your minimum calibration schedule during a seven day sensor session is shown below:

Example Minimum Calibration Schedule During Seven-Day Sensor Session

Monday (Day One of Sensor Session):



Tuesday - Sunday (Days 2-7 Sensor Session):



HELPFUL HINTS:

- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration as alternative site blood glucose values may be different than those obtained from a fingerstick blood glucose value. Use a blood glucose value obtained only from a blood glucose meter for calibration.
- In order to obtain accurate sensor glucose readings proper calibration is required using accurate blood glucose values.

4.2 HOW TO CALIBRATE

For calibration, you must enter the exact blood glucose value from your meter. Blood glucose values must be between 2.2-22.2 mmol/L and must have been taken within the past 5 minutes.



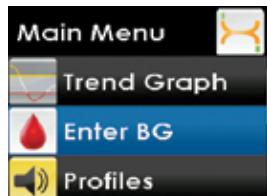
Entering incorrect blood glucose values, or blood glucose values that occurred more than 5 minutes ago may cause inaccurate sensor glucose readings.

HELPFUL HINT:

- Only blood glucose values between 2.2-22.2 mmol/L can be used for calibration. If the blood glucose value(s) you entered was outside of this range, the receiver will not calibrate. You will have to wait until your blood glucose is in this range to calibrate.

The steps below show you how to enter your blood glucose values for calibration:

1. Take a blood glucose measurement using your meter.
2. From any trend graph, press the **SELECT** button to display the main menu.
3. Use the **UP** or **DOWN** button to scroll until you highlight "Enter BG."
4. Press the **SELECT** button to choose this option. You will see a screen with a blood drop and a number in mmol/L units.



HELPFUL HINT:

- “Enter BG” will be the second main menu option when you are in the middle of a sensor session.

- When the receiver does not have a recent sensor glucose reading the default is 6.7 mmol/L.
- If there has been a sensor glucose reading in the past 15 minutes, the “Enter BG” screen will display your current sensor glucose reading as your starting point. **Do not use the current sensor glucose reading for calibration.** Use only blood glucose values from your meter.
- Before you take a blood glucose measurement to be used for calibration, wash your hands, make sure your glucose test strips are not expired and have been stored properly, and that your meter is properly coded (if required).

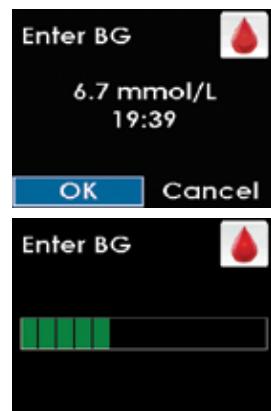


Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.

5. To enter the blood glucose value, use the **UP** or **DOWN** button to scroll until you see the correct value and then press the **SELECT** button.
6. **Confirm that the blood glucose value you entered is correct. Entering incorrect values may affect the sensor accuracy.**

- If the blood glucose value displayed is correct, press the **SELECT** button.
- If the blood glucose value displayed is incorrect, press the **RIGHT** button to highlight “Cancel” then press the **SELECT** button to return to the “Enter BG” screen. Repeat the steps for re-entering the correct blood glucose value.
- If you do not press the **SELECT** button, the receiver will “time out” and no blood glucose value will be recorded for calibration.

7. The “Enter BG” processing screen will appear to let you know the blood glucose value is being processed for calibration.



8. For startup calibration, repeat these steps for the second blood glucose value.
9. A sensor glucose reading will appear on the receiver right away, and sensor glucose readings will be updated every 5 minutes.
10. If readings do not appear immediately, see Chapter 9, Section 9.2, Calibration Troubleshooting.

HELPFUL HINTS:

- Before calibration make sure a sensor glucose reading or a blood drop symbol  is displayed at the top of the trend graph.
- Due to the potential for confusion from low glucose, you may want to treat low blood glucose prior to calibrating.
- Always make sure the antenna symbol  is displayed in the upper left corner of the trend graph before you enter blood glucose values for calibration.
- You should always use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy may vary between blood glucose meter brands.
- The accuracy of the blood glucose meter measurement used for calibration may affect the accuracy of sensor glucose readings.
- Do not calibrate your Dexcom G4 PLATINUM System when you have acetaminophen (paracetamol) active in your body. Taking acetaminophen (paracetamol) containing products (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen (paracetamol) active in your body.



Your sensor glucose readings may be inaccurate if you calibrate less than every 12 hours.

You must enter the exact blood glucose value that your blood glucose meter displays. Enter all blood glucose values for calibration within 5 minutes. Entering incorrect blood glucose values, or blood glucose values that occurred more than 5 minutes ago, will affect device performance and may cause inaccurate sensor glucose readings.

4.3 STARTUP CALIBRATION

Two hours after you start the sensor session (see Chapter 3, Section 3.7, Starting a Sensor Session) the receiver will tell you that you need to calibrate by displaying the startup calibration prompt. This prompt means you need to calibrate with 2 separate blood glucose values from your meter. You will not see sensor glucose readings until the receiver accepts the blood glucose values.



Startup calibration prompt

1. When you see this screen, press the **SELECT** button to clear the display.
2. Take 2 separate blood glucose measurements with your meter and enter the blood glucose values into the receiver (see Chapter 4, Section 4.2, How to Calibrate).
3. You can clear the prompt by pushing the **SELECT** button. The blood drop symbol will remain at the top of the trend graph until you calibrate. The system will re-alert you every 15 minutes until you enter the blood glucose values. You will not receive sensor glucose readings until the receiver accepts the blood glucose values.

If you do not clear the prompt, the system will re-alert you every 5 minutes.

4.4 12 HOUR CALIBRATION UPDATE

Calibrate your system every 12 hours after your initial calibration (performed at 2 hours after sensor insertion) to make sure your sensor glucose readings remain accurate and are close to your blood glucose meter values. You can enter any blood glucose values you take during a sensor session. If you have not entered any blood glucose values in the past 12 hours, the receiver will ask you to enter a blood glucose value to update its calibration. The following steps show you how to enter this calibration.



Your sensor glucose readings may be inaccurate if you calibrate less than every 12 hours.

- When you see this calibration prompt it means it is time to calibrate with a single blood glucose value. You can clear the prompt by pushing the **SELECT** button. The system will re-alert you every 15 minutes until the receiver accepts the blood glucose value.
- Take 1 blood glucose measurement with your meter and enter the blood glucose value into the receiver. If this screen reappears shortly after you have entered a new blood glucose value see Chapter 9, Section 9.2, Calibration Troubleshooting.



Calibration prompt

4.5 OTHER REASONS YOU MAY NEED TO CALIBRATE

- When your system did not accept the last calibration.
- When your blood glucose value is very different from the sensor glucose reading.

- When you see this calibration prompt it means it is time to calibrate with a single blood glucose value.
- Take 1 blood glucose measurement with your meter and enter the blood glucose into the receiver. If this screen reappears shortly after you have entered a new blood glucose value see Chapter 9, Section 9.2.1, Types of Calibration Prompts.



Calibration prompt

HELPFUL HINT:

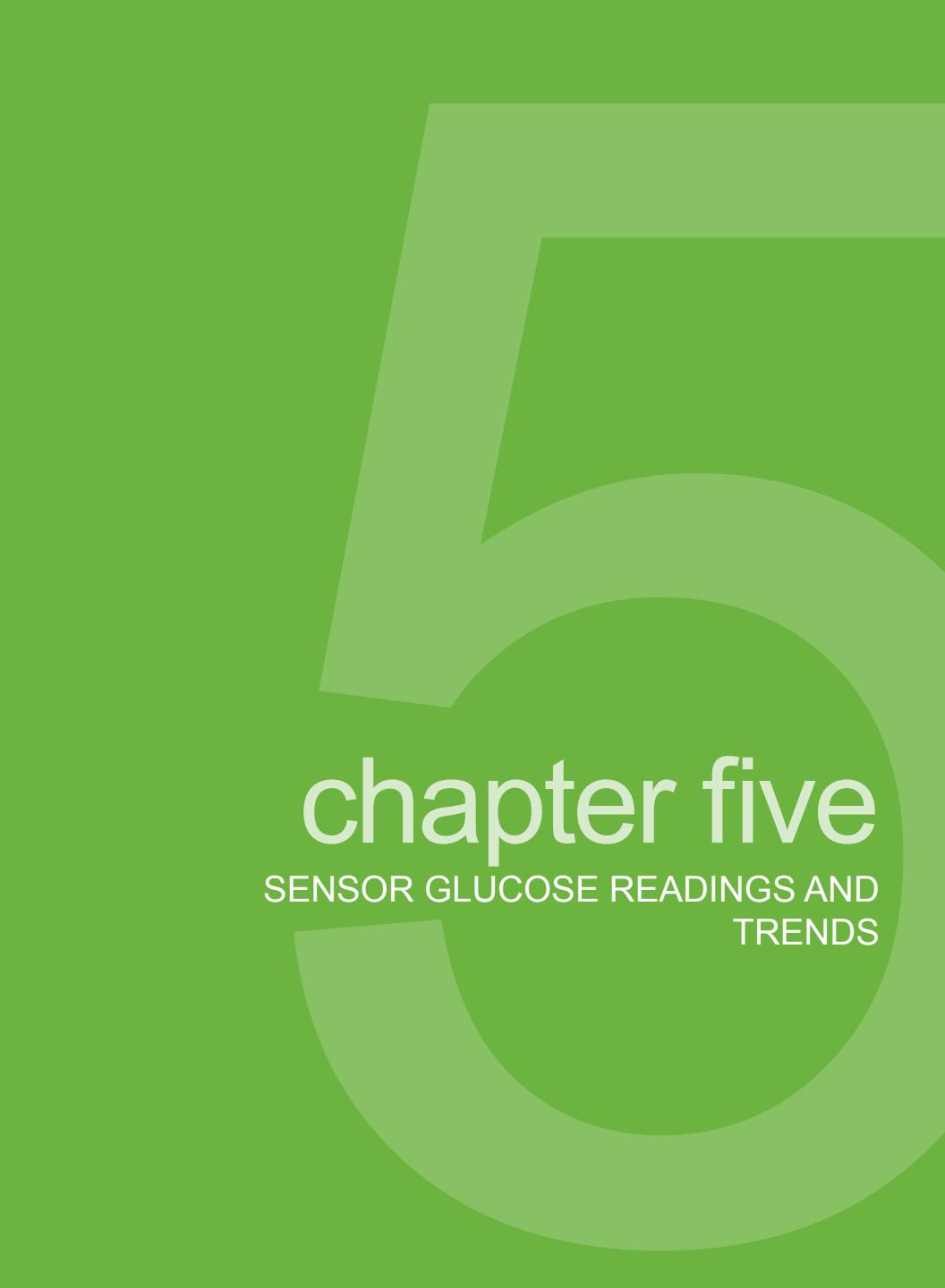
If you see these screens they are indicating calibration errors (see Chapter 9, Section 9.3, Calibration Error Troubleshooting).



15 minute calibration error screen



1 hour calibration error screen



chapter five

SENSOR GLUCOSE READINGS AND
TRENDS

This chapter will teach you how to view your sensor glucose readings and trend information. The trend graph will provide additional information that your blood glucose meter does not. It shows your current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where your glucose has been over time.



Taking acetaminophen (paracetamol) containing products (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen (paracetamol) active in your body.

Your blood glucose meter and sensor measure your glucose from two different types of body fluids: blood and interstitial fluid. Therefore, your readings from your blood glucose meter and sensor may not match.

HELPFUL HINTS:

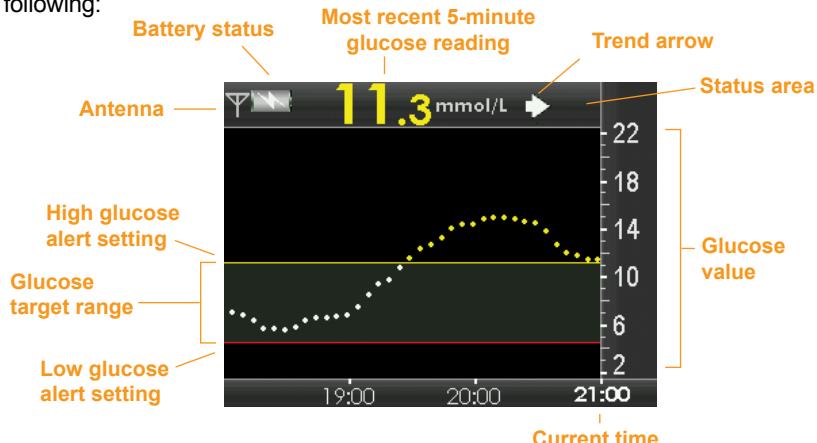
- The greatest benefit you receive from using your Dexcom G4 PLATINUM System will come from the trending information. It is important that you focus on the trends and rate of change on your receiver, rather than the exact glucose reading.
- If you have difficulty reading your receiver in bright sunlight, you may need to seek a shady location.



The blood glucose value from your blood glucose meter should be used for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM System does not replace a blood glucose meter. Blood glucose values may differ from sensor glucose readings. The direction, rate of glucose change, and trend graph on your Dexcom G4 PLATINUM System provide additional information to help with your diabetes management decisions.

5.1 Sensor Glucose Readings

Press the **SELECT** button to wake up the receiver screen. You will see the home screen, which is the 3-hour trend graph. The 3-hour trend graph will show the following:



- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- The trend graph shows the current time.
- The display light is activated with a press of any button.
- The status area shows needed calibration updates, calibration errors and sensor glucose reading issues.
- Your high alert setting will be displayed as a yellow line across the trend graph.
- Your low alert will be displayed as a red line across the trend graph.
- The gray zone highlights your target glucose range based on your individualized settings for high and low glucose alerts.
- Your current glucose reading will be red if it is low and yellow if it is high, based on your high and low glucose alert settings.
- The dots on your trend graph will also change colors based on your high and low alert settings.
- If your low glucose alert is not set and your glucose is 3.1 mmol/L or lower, your glucose value will be red.
- If your sensor glucose readings are in between your high and low glucose alert settings, the glucose value will be white.

You can view your past glucose information through the 1, 3, 6, 12, and 24 hour trend graphs by pressing the **UP** or **DOWN** button.

- Your system only reports glucose information between 2.2-22.2 mmol/L. Your trend graph will show a flat line or dots at 22.2 or 2.2 mmol/L when your glucose is outside this range.



The sensor glucose reading is in millimoles per liter (mmol/L) unit

(Scroll up from the 3-hour graph to reach the 1-hour graph)



1-Hour Trend Graph: The 1-hour trend graph shows your current glucose reading and the last 1 hour of sensor glucose readings.



3-Hour Trend Graph: The 3-hour trend graph shows your current glucose reading and the last 3 hours of sensor glucose readings.

(Scroll down from the 3-hour graph to reach the 6-hour graph)



6-Hour Trend Graph: The 6-hour trend graph shows your current glucose reading and the last 6 hours of sensor glucose readings.

(Scroll down from the 6-hour graph to reach the 12-hour graph)



12-Hour Trend Graph: The 12-hour trend graph shows your current glucose reading and the last 12 hours of sensor glucose readings.

(Scroll down from the 12-hour graph to reach the 24-hour graph)



24-Hour Trend Graph: The 24-hour trend graph shows your current glucose reading and the last 24 hours of sensor glucose readings.

The receiver displays “LOW” when the most recent glucose reading is less than 2.2 mmol/L and “HIGH” when the most recent glucose reading is greater than 22.2 mmol/L.



5.2 RATE OF CHANGE ARROWS

Your rate of change arrows add detail about the direction and speed your glucose is changing.

The trend arrows appear to the right of your current glucose reading.



HELPFUL HINT:

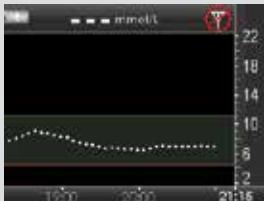
- Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, your overall trend graph and your blood glucose value before taking action.

This table shows the different trend arrows your receiver will display:

	Constant: Your glucose is steady (not increasing/decreasing more than 0.06 mmol/L each minute). Your glucose could increase or decrease by up to 0.8 mmol/L in 15 minutes.
	Slowly rising: Your glucose is rising 0.06-0.11 mmol/L each minute. If it continued rising at this rate, your glucose could increase up to 1.7 mmol/L in 15 minutes.
	Rising: Your glucose is rising 0.11-0.17 mmol/L each minute. If it continued rising at this rate, your glucose could increase up to 2.5 mmol/L in 15 minutes.
	Rapidly rising: Your glucose is rising more than 0.17 mmol/L each minute. If it continued rising at this rate, your glucose could increase more than 2.5 mmol/L in 15 minutes.
	Slowly falling: Your glucose is falling 0.06- 0.11 mmol/L each minute. If it continued falling at this rate, your glucose could decrease up to 1.7 mmol/L in 15 minutes.
	Falling: Your glucose is falling 0.11-0.17 mmol/L each minute. If it continued falling at this rate, your glucose could decrease up to 2.5 mmol/L in 15 minutes.
	Rapidly falling: Your glucose is falling more than 0.17 mmol/L each minute. If it continued falling at this rate, your glucose could decrease more than 2.5 mmol/L in 15 minutes.
No arrow	No rate of change information: The receiver cannot calculate how fast your glucose is rising or falling at this time.

HELPFUL HINTS:

- Trend arrows do not appear when there are glucose data gaps (see Chapter 9, Section 9.4, System Glucose Error). If the glucose reading error symbol , the wait symbol , the out of range symbol , or the blood drop symbol , appear at the top of the trend graph, the trend arrows will not appear.
- If the trend arrow is missing, but you are concerned that your blood glucose level may be rising or falling, take a blood glucose measurement test on your blood glucose meter.



Symptoms related to low or high blood glucose levels should not be ignored. If you have symptoms of low or high glucose obtain a blood glucose measurement from your meter.

5.3 GLUCOSE STATUS AREA SYMBOLS

During your sensor session the “status area” at the top of the trend graph may display any of the status symbols below. You will not receive sensor glucose readings during the time the status symbol is displayed except during the regular 12 hour calibration prompt.

 Calibration Needed	<p>This icon means you need to enter a calibration. This prompt will appear when it is time for your 12 hour calibration update or any other time an additional calibration is needed (see Chapter 4, Section 4.2, How to Calibrate).</p>
 Additional Calibration Needed	<p>This icon means you need to enter one more blood glucose value in order to calibrate the system and start receiving sensor glucose readings.</p>

 Glucose Reading Error	<p>This icon means the receiver does not understand the sensor signal temporarily. This icon is related to the sensor only. You should wait for more prompts and do not enter any blood glucose values when you see this symbol.</p>
 Out of Range	<p>This icon means the receiver and sensor/transmitter are not communicating. Make sure the receiver and sensor/transmitter are within 6 meters of each other (see Chapter 1, Section 1.2, Transmitter Overview).</p>
 15 Minute Calibration Error	<p>This icon means the sensor cannot calibrate right now. If you see this screen, enter at least one more calibration blood glucose value after about 10-15 minutes. If the sensor still cannot calibrate after that, the sensor needs to be removed and a new sensor needs to be inserted.</p>
 1 Hour Calibration Error	<p>This icon means the sensor is not calibrating correctly. If you see this screen, wait a minimum of one hour and then enter one more blood glucose value. If no readings display on the receiver after this, the sensor needs to be removed and a new sensor needs to be inserted.</p>
 Wait	<p>This icon means the receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values when you see this symbol.</p>

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chapter six

ALERTS, ALARMS AND ALERT PROFILES

This chapter will teach you about your Dexcom G4 PLATINUM CGM System's many alerts and alarms and how to customize them.

6.1 SETTING YOUR ALERTS

6.1.1 DEFAULT ALERT/ALARM SETTINGS

When you receive your Dexcom G4 PLATINUM CGM System the following alerts and alarms are preset on your receiver (see table below).

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	<p>High Glucose Alert Your most recent sensor glucose reading is at or above the high alert setting.</p>	On at 11.1 mmol/L	Vibrates twice then vibrates/beeps twice every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high alert snooze feature.
	<p>Low Glucose Alert Your most recent sensor glucose reading is at or below the low alert setting.</p>	On at 4.4 mmol/L	Vibrates three times then vibrates/beeps three times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low alert snooze feature.
	<p>Fixed Low Alarm Your most recent sensor glucose reading is at or below 3.1 mmol/L.</p>	On	Vibrates four times then vibrates/beeps four times every five minutes until confirmed or your glucose value goes above 3.1 mmol/L.	Yes, every 30 minutes after each confirmation until your blood glucose value comes back into range.

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	Out of Range Alert The Sensor/Transmitter and Receiver are not communicating to each other.	Off	Off	No
 	Rise/Fall Alert Single Arrow Your glucose is rising/falling at or above a rate of 0.11 mmol/L/min (at least 1.7 mmol/L in 15 minutes).	Off	Off	No
 	Rise/Fall Alert Double Arrow Your glucose is rising/falling at or above a rate of 0.17 mmol/L/min (at least 2.5 mmol/L in 15 minutes).	Off	Off	No

HELPFUL HINT:

- Your receiver may alert you at other times you need to take action such as low battery, failed sensor, etc. See Chapter 12, Appendix, for a detailed list of these other alerts.

6.1.2 GLUCOSE ALERTS

The Dexcom G4 PLATINUM System lets you create your own personal settings for how you want the receiver to tell you what is going on. The low and high glucose alerts will tell you when your sensor glucose readings are outside your target glucose range. Rise and fall (rate of change) alerts let you know when your glucose levels are changing fast (see Chapter 6, Section 6.2, Advanced Alerts). The Dexcom G4 PLATINUM System also features a low glucose alarm that cannot be adjusted or turned off and is set at 3.1 mmol/L. This is a safety feature telling you your glucose level may be dangerously low. In addition to the alert screens that appear on your receiver display, you can also set high and low glucose alerts to notify you with vibrations and beeps. This feature can be helpful during times such as sleeping, driving, exercising, or during meetings.

6.1.3 HIGH GLUCOSE ALERT

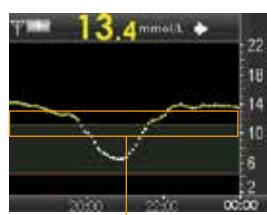
When your sensor glucose readings are at or above your high alert level, this screen will appear with your high glucose alert value displayed. Your receiver will vibrate and/or beep depending on your profile setting (see Chapter 6, Section 6.3, Alert Profiles).

When you set the high glucose alert, this level is indicated by a yellow line on the trend graph.

The receiver will continue to alert you until you press the **SELECT** button to clear the alert, or until your sensor glucose readings drop below your high glucose alert level. You can choose to have the receiver re-alert you after clearing the alert by changing your snooze settings (see Chapter 6, Section 6.2, Advanced Alerts).



High glucose alert set at 11.1 mmol/L



High glucose alert setting

6.1.4 LOW GLUCOSE ALERT

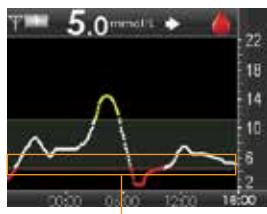
When your sensor glucose readings are at or below your low alert level, this screen will appear with your low glucose alert value displayed. Your receiver will vibrate and/or beep depending on your profile setting.

When you set the low glucose alert, this level is indicated by a red line on the trend graph.



Low glucose alert set
at 4.4 mmol/L

The receiver will continue to alert you until you press the **SELECT** button to clear the alert, or until your sensor glucose readings rise above your low glucose alert level. You can choose to have the receiver re-alert you after clearing the alert, by changing your snooze settings (see Chapter 6, Section 6.2, Advanced Alerts).



Low glucose alert setting

HELPFUL HINTS:

- When you have both your high and low alerts turned on there will be a gray zone on your trend graphs indicating your target range.
- If your high or low alert is turned off this gray zone will not appear.

6.1.5 LOW GLUCOSE ALARM

The Dexcom G4 PLATINUM System also has a fixed low alarm set at 3.1 mmol/L. This alarm is a feature in addition to your personal low and high glucose alerts. You cannot change or turn off this alarm or its re-alarm settings.

- For the low glucose alarm the receiver will display the screen to the right.
- Re-alarm: The receiver will automatically notify you again in 30 minutes after you press the **SELECT** button to clear it, if your sensor glucose readings are still at or below 3.1 mmol/L.

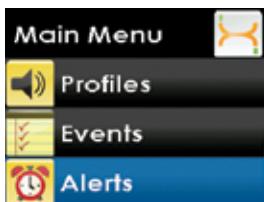


HELPFUL HINT:

- Your receiver will not alert you if you have calibrated in the last 5 minutes and received a sensor glucose reading outside your target range. The receiver will alert you if your sensor glucose reading remains outside your target range after five minutes.

6.1.6 GETTING TO THE ALERTS MENU

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will appear.
2. Press the **SELECT** button to display the main menu.
3. From the main menu, press the **UP** or **DOWN** button to scroll to “Alerts” and press the **SELECT** button. The alerts menu will appear.



6.1.7 HIGH AND LOW GLUCOSE ALERTS

HELPFUL HINT:

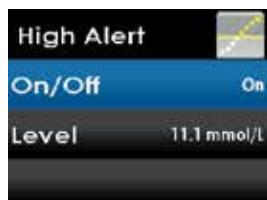
- The steps for setting both the high alert and the low alert are the same.

The following steps show you how to change your high and low alert settings.

- From the alerts menu, press the **UP** or **DOWN** button to select “High Alert” or “Low Alert” and press the **SELECT** button.

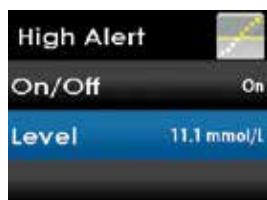


- Press the **UP** or **DOWN** button to highlight “On/Off” then press the **SELECT** button to set this option. A check mark will appear next to the current setting.



- Press the **LEFT** button to return to the previous screen.

- Press the **DOWN** button to highlight “Level.” The number displayed is your current high glucose alert value setting. To change this number press the **SELECT** button and then press the **UP** or **DOWN** button until your desired high glucose alert value is displayed, then press the **SELECT** button.



- Your high glucose alert value can be set between 6.7 and 22.2 mmol/L in 0.1 mmol/L increments.
- Your low glucose alert value can be set between 3.3 and 5.5 mmol/L in 0.1 mmol/L increments.



HELPFUL HINT:

- Alerts must be acknowledged by pressing the SELECT button on the receiver.

6.2 ADVANCED ALERTS

In addition to your high and low alerts and alarm, the high and low snooze, rise and fall rate and out of range alerts may be set. For any of these advanced alerts follow the steps below.

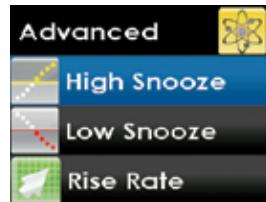
1. Turn the receiver on by pressing the **SELECT** button.
2. Press the **SELECT** button to enter the main menu.
3. Press the **UP** or **DOWN** button to highlight “Alerts” and press the **SELECT** button.
4. From the alerts menu, press the **UP** or **DOWN** button to select “Advanced” and press the **SELECT** button.



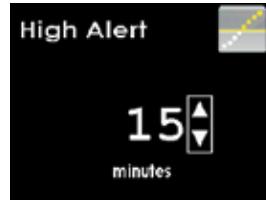
6.2.1 SETTING A SNOOZE TIME FOR YOUR HIGH AND LOW GLUCOSE ALERTS

You have the option to set a snooze time, every 15 minutes for up to 5 hours, in between your high and low glucose re-alerts.

1. Press the **UP** or **DOWN** button to choose “High Snooze” or “Low Snooze” and press the **SELECT** button.



2. Press the **UP** or **DOWN** button to select the amount of time (in 15 minute increments) in between the first alert and re-alerts. Press the **SELECT** button. If you set the amount of time to zero there will be no re-alerts.
3. When finished, press the **LEFT** button to return to the alerts menu.



6.2.2 RISE AND FALL GLUCOSE RATE ALERTS

Rate alerts notify you when your glucose levels are rising (rise alert) or falling (fall alert), and by how much. You can choose whether your receiver alerts you when your sensor glucose value is either rising or falling 0.11 mmol/L or more per minute, or 0.17 mmol/L or more per minute.

If you set your fall rate to 0.11 mmol/L per minute and your sensor glucose readings fall at this rate or faster, the “FALLING single arrow” screen will appear and the receiver will vibrate or beep according to your profile settings.



Fall alert

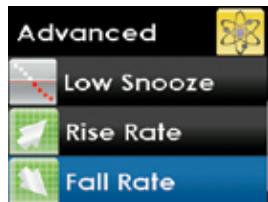
If you set your rise rate to 0.17 mmol/L per minute and your sensor glucose readings rise at this rate or faster, the “RISING double arrow” screen will appear and the receiver will vibrate or beep according to your profile settings.



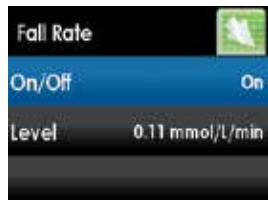
Rapid rise alert

The following steps show you how to change your rise or fall rate alert settings.

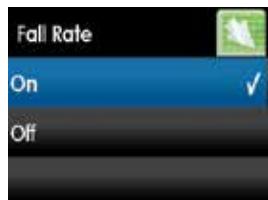
1. Press the **UP** or **DOWN** button to choose “Rise Rate” or “Fall Rate” and press the **SELECT** button.



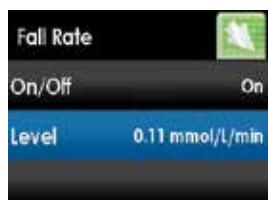
2. Press the **UP** or **DOWN** button to highlight “On/Off,” then press the **SELECT** button.



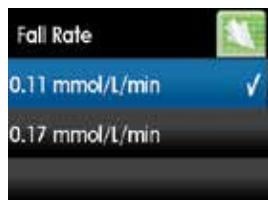
3. Press the **UP** or **DOWN** button to choose “On” or “Off.” Then, press the **SELECT** button to select “On” or “Off.”



4. Press the **LEFT** button to go back to the previous screen. Press the **UP** or **DOWN** button to select “Level” then press the **SELECT** button. Choose whether the alerts should be delivered when your glucose levels are rising/falling either “0.11 mmol/L/min” (0.11 mmol/L or more per minute) or “0.17 mmol/L/min” (0.17 mmol/L or more per minute). Press the **SELECT** button.



5. When finished, press the **LEFT** button to return to the alerts menu.



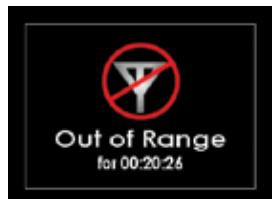
HELPFUL HINT:

- You confirm alerts by pressing the SELECT button on the receiver.

6.2.3 SETTING THE OUT OF RANGE ALERT

The out of range alert lets you know when the sensor/transmitter and receiver are not communicating with each other. Typically, you should keep the sensor/transmitter and receiver within 6 meters of each other. When the sensor/transmitter and receiver are too far apart and are not communicating, you will not receive sensor glucose readings from the sensor.

When this happens, the out of range symbol  will appear in the upper right corner of the trend graph and the screen to the right will appear. The amount of time the devices are out of range will appear on the out of range alert screen.



1. Press the **UP** or **DOWN** button to choose “Out of Range” and press the **SELECT** button.



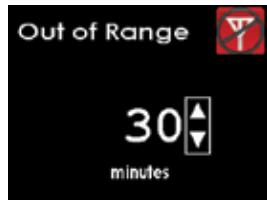
2. On the out of range menu, press the **UP** or **DOWN** button to choose “On/Off.” Then, press the **SELECT** button to select “On.” If you do not want to receive out of range alerts press the **SELECT** button to choose “Off.”



3. Next, on the out of range menu, press the **UP** or **DOWN** button to choose “Time” and press the **SELECT** button.



4. Press the **UP** or **DOWN** button to choose the elapsed time, after which the receiver will alert you and continue to re-alert you until you are back in range. Press the **SELECT** button.
5. When finished, press the **LEFT** button to return to the alerts menu.



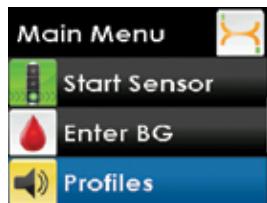
6.3 ALERT PROFILES

The Dexcom G4 PLATINUM System allows you to set profiles to choose the way you want your alerts to behave. This customizable feature is found under the Profiles option on the Main Menu shown to the right.

You can set your profile to the sound pattern and the volume level that best fits your lifestyle needs. Depending on your daily activities, you can quickly and easily change the way your system alerts you by changing your profile settings.

Your profile options are:

1. Vibrate
2. Soft
3. Normal
4. Attentive
5. HypoRepeat



For each profile option you will first be alerted by a vibration.

When you choose your profile setting it is important to know this setting will apply to all alerts, alarms and prompts. Within each profile setting each specific alert will have its own unique sound pattern, tone and volume level. This allows you to easily identify each alert and alarm and its meaning.

HELPFUL HINTS:

- On the first alert notification the receiver will vibrate only (no beep). Regardless of the specific alert profile you chose, if you confirm the initial vibrate alert, you will not receive an additional audible alert.
- The fixed low alarm at 3.1 mmol/L cannot be turned off or adjusted.
- For the soft, normal, attentive and HypoRepeat profiles the following alert sequence will occur:
 - The first alert is vibrate only.
 - If the alert is not confirmed in five minutes, the system will vibrate and beep.
 - If the alert is not confirmed in five more minutes, the system will vibrate and beep louder and this will continue at the same volume level every five minutes until confirmed.

For the HypoRepeat profile only:

- If the alert is confirmed and your sensor glucose readings continue to be at or below 3.1 mmol/L your system will repeat the alert sequence above in 30 minutes.

To confirm any alert press the SELECT button.

6.3.1 ALERT PROFILE OPTIONS



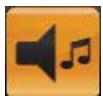
The vibrate profile can be used when you want to silence the receiver and be alerted by vibration. The only exception to this will be with the fixed low alarm at 3.1 mmol/L, which will alert you as a vibration first, followed by audible beeps 5 minutes later if not confirmed.



The soft profile can be used when you need your alert to be discreet. This profile sets all the alerts and alarms to lower volume beeps, which is intended to be less noticeable by people around you.



This normal profile is the default profile when you receive your system. This profile sets all the alerts and alarms to higher volume beeps.

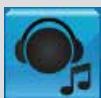


The attentive profile can be used when you need your alert to be the most noticeable. This profile sets all the alerts and alarms to loud and highly distinctive melodies.



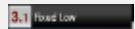
The HypoRepeat profile is very similar to the normal profile. The difference with this profile is it will continuously repeat the fixed low alarm every 5 seconds until your sensor glucose value rises above 3.1 mmol/L or if it is confirmed. This profile can be helpful if you want an additional level of awareness when you have severe low sensor glucose readings.

HELPFUL HINT:



The “Try It” feature is available under the profiles menu and allows you to hear an example of the alert sequence and sound for each individual alert and alarm. Once you hear the sounds, it is easier to understand the alert profile options.

6.3.2 ALERT PROFILE DETAILS

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE	HYPOREPEAT
High Alert 	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + ascending melody	2 long vibrates + 2 medium beeps
Low Alert 	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + descending melody	3 short vibrates + 3 medium beeps
Rise Alert 	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 1 short ascending melody	2 long vibrates + 2 medium beeps
Fall Alert 	3 short vibrates	3 short vibrates + 3 low beep	3 short vibrates + 3 medium beeps	3 short vibrates + 2 short descending melodies	3 short vibrates + 3 medium beeps
Out of Range Alert 	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 3 short repeating melodies	1 long vibrate + 1 medium beep
Fixed Low 	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrate + 4 medium tone beeps	4 short vibrates + 2 long descending melodies + pause + 4 low beeps	4 short vibrates + 4 low beeps + pause + repeat sequence
All Other Alerts	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 short melody	1 long vibrate + 1 medium beep

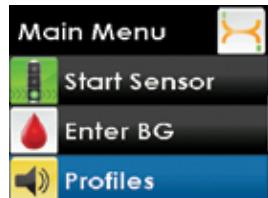
6

The following steps show you how to access and choose the profile you want to set.

1. Press the **SELECT** button to turn on the receiver.
The 3-hour trend graph will appear.



2. Press the **SELECT** button to display the main menu.
3. From the main menu, press the **UP** or **DOWN** button to scroll to “Profiles” and press the **SELECT** button. The profiles menu will appear.



4. Press the **UP** or **DOWN** button to scroll to the profile you want to set and press the **SELECT** button.
5. When finished, press the **LEFT** button to return to the main menu.



chapter seven

EVENTS

The Events feature allows you to record information about your diabetes management that may help you and your healthcare professionals better understand your glucose patterns and trends. You can enter details about carbohydrate intake, insulin intake, exercise, and issues related to your health. You can then view your trends and track your patterns using the Dexcom Studio software.

7.1 EVENTS

HELPFUL HINT:

- Event markers can be downloaded and viewed in the Dexcom Studio software but cannot be viewed on your receiver.

7.1.1 SELECTING AN EVENT

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will appear.
2. Press the **SELECT** button to display the main menu.
3. From the main menu, press the **UP** or **DOWN** button to scroll to “Events” and press the **SELECT** button. The events menu will appear.



4. Press the **UP** or **DOWN** button to choose the event you want, “Carbs,” “Insulin,” “Exercise” or “Health” and press the **SELECT** button.



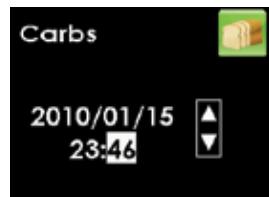
7.1.2 SETTING THE DATE AND TIME FOR AN EVENT

When you enter an event you will be prompted to check that the date and time for that event are correct. The default date and time for events you enter is the current date and time stored in the receiver. The date format is YYYY/MM/DD.

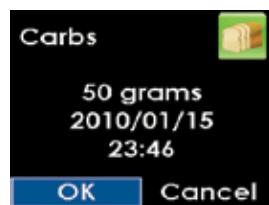
HELPFUL HINT:

- If you change the date or time for any event, it only applies to that event and will not change the current date and time in your receiver.

1. To change the date and time for an event, press the **RIGHT** button to highlight each value in the date and time. Then, press the **UP** or **DOWN** button to make any adjustments and then press the **RIGHT** button to move to the next value. After adjusting the time, press the **SELECT** button.



2. You will advance to the event confirmation screen. Press the **SELECT** button to confirm the entry.



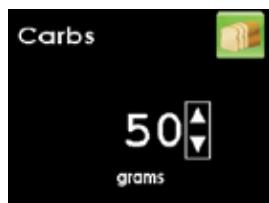
7.1.3 CARBOHYDRATES

The carbs event lets you enter the amount of carbohydrates you have consumed, up to 250 grams.

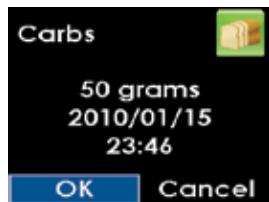
1. From the events menu press the **UP** or **DOWN** button to choose “Carbs” and press the **SELECT** button.



2. Press the **UP** or **DOWN** button to enter your carb amount (0-250 grams), and press the **SELECT** button. The number that first appears on this screen will be the last number you entered or the default amount of 50 grams.



3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm the entry.
4. You will advance to the event confirmation screen. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



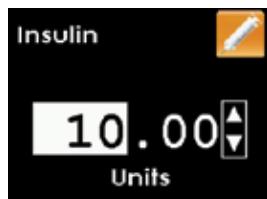
7.1.4 INSULIN

The insulin event lets you enter the amount of insulin you have taken, up to 250 units. You can only enter an insulin amount, not the type of insulin taken.

1. From the events menu press the **UP** or **DOWN** button to choose “Insulin” and press the **SELECT** button.

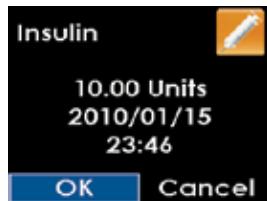


2. Press the **UP** or **DOWN** button to enter your insulin amount (0-250 units), and press the **SELECT** button. The number that first appears on this screen will be the last number you entered or the default amount of 10 units.



3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm the entry.

4. You will advance to the event confirmation screen. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



7.1.5 EXERCISE

The exercise event lets you enter the intensity (light, medium, or heavy) and duration (up to 360 minutes), for any particular date and time.

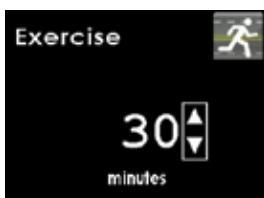
1. From the events menu press the **UP** or **DOWN** button to choose “Exercise”, and press the **SELECT** button.



2. Press the **UP** or **DOWN** button to choose your exercise intensity level, and press the **SELECT** button.

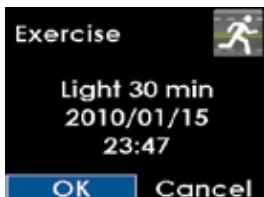


3. Press the **UP** or **DOWN** button to enter your exercise duration (0-360 minutes), and press the **SELECT** button. The number that first appears on this screen is the default amount of 30 minutes.



4. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm the entry.

5. You will advance to the event confirmation screen. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the events menu.



7.1.6 HEALTH

The health event lets you enter episodes of illness, stress, high symptoms, low symptoms, cycle (menstrual) or alcohol consumption, for any particular date and time.

1. From the events menu press the **UP** or **DOWN** button to choose “Health,” and press the **SELECT** button.

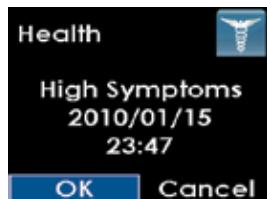


2. Press the **UP** or **DOWN** button to choose your health event, and press the **SELECT** button.



3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm the entry.

4. You will advance to the event confirmation screen. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the events menu.



7.2 DEXCOM STUDIO SOFTWARE

The Dexcom Studio software is an optional component of your system. This software allows you to view trends, track patterns and create customizable charts to display your glucose trends.

You can change the date ranges to view long or short term patterns and trends. You can use data from current and previous system downloads and save or print files that you and your healthcare professionals can review.

For system requirements refer to the Dexcom website (www.dexcom.com). The Dexcom Studio Software User's Guide gives you more information on how to use this software.



chapter eight

COMPLETING A SENSOR SESSION

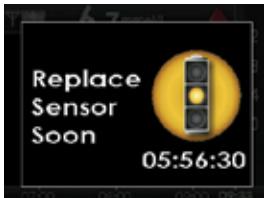
Your sensor will continue to give you sensor glucose readings for up to seven days. The performance of a sensor has not been tested beyond seven days.

HELPFUL HINTS:

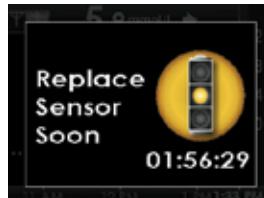
- Do not remove the transmitter from the sensor pod while the pod is attached to your skin.
- Do not dispose of your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life.
- Consult your local waste management authorities for appropriate procedures for disposal of blood contacting components (sensor and applicator).
- In some cases your sensor session may end before you have completed a full 7-day period. If this happens, see Chapter 9, Section 9.6, Sensor Shut-Off Troubleshooting.

8.1 AUTOMATIC SENSOR SHUT-OFF

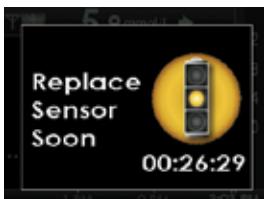
The receiver will tell you how much time you have remaining until your sensor session is complete. The sensor expiration screen will appear at 6 hours, 2 hours and 30 minutes before your 7-day sensor session ends.



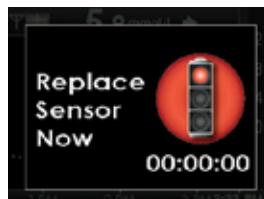
6-hour sensor expiration notification screen



2-hour sensor expiration notification screen



30-minute sensor expiration notification screen



Sensor expiration notification end of session screen

You can set the receiver to alert you with these displays using the profiles setting (see Chapter 6, Section 6.3, Alert Profile Details, “All Other Alerts”). After the 6-hour, 2-hour, and 30-minute reminders, you will continue to receive sensor glucose readings. You can clear these screens by pressing **SELECT** on the receiver. You must remove your sensor after the final sensor expiration screen (00:00:00) appears.

Once your sensor session has ended, sensor glucose readings will no longer be shown on the receiver. The trend graphs will indicate that the sensor session has ended by displaying a red stoplight symbol at the top as shown in the screen to the right.

You will need to remove your sensor and insert a new sensor.



HELPFUL HINT:

- Glucose level alerts and alarms will not function after the sensor session has ended.

8.2 REMOVING A SENSOR



Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to your local distributor.

When you are ready to remove the sensor, make sure to pull out the sensor pod while the transmitter is still attached.

1. Gently peel up the sensor pod adhesive patch from your skin, this will pull out your sensor.

8.3 TRANSMITTER REMOVAL

Once the sensor pod is off your body, you will need to remove the transmitter (**do not dispose of the transmitter**). To remove the transmitter you can use either of the two methods below:

Method 1

The safety lock, once removed from the applicator (see Chapter 3, Section 3.4 Placing the Sensor), can be used as a tool to remove the transmitter.

1. Place the sensor pod on a table.
2. Hold the rounded edge of the safety lock.
3. Make sure the jagged edge of the safety lock is facing down (the direction away from the removal arrow) as shown below:



4. Insert the jagged edges so that they “hug” the wide end of the transmitter in the sensor pod. Press the safety lock down until you cannot press down anymore, and the transmitter will “pop” out of the sensor pod.
5. Remove the transmitter, clean it (see Chapter 10, Section 10.1, Maintenance) and store it in a cool, dry place until your next glucose monitoring session.

Method 2

If you did not save the safety lock, you can simply use your fingers to spread out the tabs at the back of the sensor pod (end closest to the sensor pod tab wings). The transmitter will “pop” out of the sensor pod.

chapter nine

TROUBLESHOOTING

This chapter provides helpful tips and instructions to resolve issues you may experience while using your Dexcom G4 PLATINUM CGM System.

HELPFUL HINT:

- If the troubleshooting steps in this chapter do not fix your issue, contact your local distributor.

9.1 SENSOR INSERTION TROUBLESHOOTING

Sensor insertion difficulties

• **I am having trouble taking out the safety lock:**

- Make sure to pull the safety lock straight out away from your body. Use the arrows on the safety lock as a guide.
- Do not wiggle back and forth.

• **I am not able to pull the collar up:**

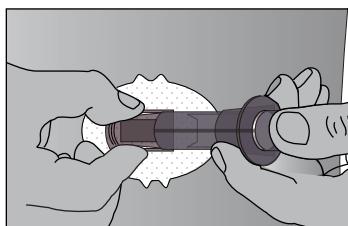
- Make sure the plunger is completely pressed down before pulling the collar up.
- When pulling the collar up you should hear 2 “clicks.”
- Try using more force when pulling the collar up.

• **I am not able to remove the applicator barrel from the sensor pod:**

- Make sure the collar is pulled all the way up. You may need to use extra force to pull the collar as close to the top of the applicator as possible.
- Make sure the transmitter latch is flat against the adhesive on your body before squeezing the release tabs.
- Then squeeze the ribbed release tabs on the sides of the sensor pod, and lift the applicator away from your body in an arc motion.

• **I am not able to remove the transmitter latch:**

- Hold the sensor pod with one hand and twist the transmitter latch with the other hand to remove it.
- Do not try to snap it straight off.



Release the applicator barrel

Sensor pod is not sticking long enough

- Make sure your skin is clear of any cream or lotion before you attach the sensor pod.
- Clean the area first with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor. Do not leave any substance on the skin where the needle inserts.
- You may use medical tape (such as Blenderm, Tegaderm, IV 3000, 3M tape) over the white adhesive patch of the sensor pod, but do not place the tape over the transmitter or the plastic parts of the sensor pod or where the needle inserts the sensor.

9.2 CALIBRATION TROUBLESHOOTING

Calibration prompts may appear during your sensor session. Review the following troubleshooting tips to have a successful calibration.

HELPFUL HINTS:

- Make sure the receiver and transmitter are communicating when you calibrate. The  icon should not appear in the status area.
- Make sure the  icon does not appear in the status area when you calibrate.
- Make sure your blood glucose values are between 2.2 and 22.2 mmol/L before you calibrate.
- Prior to obtaining a blood glucose value to be used for calibration, wash your hands, make sure your glucose test strips are not expired and have been stored properly and that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you have not taken any medications containing acetaminophen (paracetamol) (such as Tylenol).
- Make sure your transmitter is fully snapped in to your sensor pod.
- See Chapter 4, Calibration, for further information.

9.2.1 TYPES OF CALIBRATION PROMPTS

This section describes the three blood drop symbols you will see. The next section describes what to do when you see one of these symbols.

Startup calibration prompt

This prompt means the receiver's 2-hour startup period is complete. You need to enter two blood glucose values to calibrate the system and start receiving sensor glucose readings.

The receiver will continue to display the startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose values.

To clear this prompt, press the **SELECT** button.



Startup calibration prompt

Additional startup calibration prompt

This prompt means you need to enter one more blood glucose value to calibrate the system and start receiving sensor glucose readings.

The receiver will continue to display the additional startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose values.

To clear this prompt, press the **SELECT** button.



Additional startup blood drop prompt

Calibration prompt

This prompt means you need to enter one blood glucose value. This prompt will appear when it is time for your 12 hour calibration update or any other time you may need to calibrate.

The receiver will continue to display this prompt screen every 15 minutes until the receiver accepts the blood glucose values.

To clear this prompt, press the **SELECT** button.



Calibration prompt

9.2.2 STATUS AREA SYMBOLS DURING CALIBRATION PROMPTS

1. Clear the prompt from the screen by pressing the **SELECT** button.

2. Check the status area at the top of the screen. You will decide what to do based on the symbol shown in the status area:

a. If the startup calibration symbol  is displayed:

- Take 2 more blood glucose values and enter them into your receiver

b. If the additional startup calibration symbol  is displayed:

- Take 1 more blood glucose value and enter it into your receiver.

c. If the calibration needed symbol  is displayed:

- Take 1 more blood glucose value and enter it into your receiver.



Prompt in status area

9.3 CALIBRATION ERROR TROUBLESHOOTING

This screen means you recently entered a calibration blood glucose value and the sensor is having trouble calibrating. If you clear this screen by pressing the **SELECT** button this symbol  will be displayed in the status area.

If you see this screen, wait 15 minutes and then enter 1 more calibration blood glucose value. Wait 15 more minutes. If this error screen still appears enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still appears, the sensor needs to be replaced.

This screen means you recently entered a calibration blood glucose value and the sensor is having trouble calibrating. If you clear this screen by pressing the **SELECT** button, this symbol  will be displayed in the status area.



Wait 15 minute calibration error screen



Wait 1 hour calibration error screen

If you see this screen, wait at least 1 hour and then enter 1 more calibration blood glucose value. Wait 15 minutes. If this error screen still appears enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still appears, the sensor needs to be replaced.

9.4 SYSTEM GLUCOSE ERROR

Sometimes the system may tell you that it cannot provide a valid sensor glucose reading. When this occurs you will see either the glucose reading error icon  or the wait  icon in the status area. These symbols mean the receiver does not understand the sensor signal temporarily. These symbols are related to the sensor only. You should wait for more prompts and **do not enter** any blood glucose values when you see these symbols. The system will not use a blood glucose value as a calibration if it is entered when these symbols are displayed (see Chapter 5, Section 5.3, Glucose Status Area Symbols).

Troubleshooting tips before inserting your sensor:

- Make sure your sensor is not expired.
- Make sure your transmitter is fully snapped in place.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you have selected a good insertion site (see Chapter 3, Section 3.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry before sensor insertion.
- Clean the bottom of the transmitter with a slightly damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.

Often the system can correct this problem and continue providing sensor glucose readings. However, if it has been at least 3 hours since your last glucose reading appeared, contact your local distributor.



No glucose data (???)



No glucose data (wait)

9.5 SENSOR INACCURACIES

Inaccuracies are usually related to your sensor only and not your receiver or transmitter. Your sensor glucose readings are meant to be used for trending purposes only. Your blood glucose meter and sensor measure your glucose from two different types of body fluids: blood and interstitial fluid. Therefore, your readings from your blood glucose meter readings and sensor may not match.



Your sensor glucose readings may be inaccurate if you calibrate less than every 12 hours.

To calibrate the system, you must enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose value. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes ago could result in inaccurate sensor glucose readings.

If you see a difference between your sensor glucose reading and blood glucose value outside the 20%/1.1 mmol/L industry standard, wash your hands and take an additional blood glucose measurement. If the blood glucose value remains outside the industry standard, enter this blood glucose value as a calibration into your receiver. The sensor glucose reading will correct over the next 15 minutes. If you see differences between your sensor glucose readings and blood glucose values outside of this acceptable range, follow the troubleshooting tips below before inserting your next sensor:

- Make sure your sensor is not expired.
- Make sure you do not calibrate when the **???** or **!** are displayed.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration as alternative site readings may be different than those obtained from a blood glucose value. Use a blood glucose value obtained only from a fingerstick for calibration.
- Only blood glucose values between 2.2-22.2 mmol/L can be used for calibration. If one or more of your readings entered was outside of this range, the receiver will not calibrate. You will have to wait until your blood glucose is in this range to calibrate.

- You should always use the same meter you routinely use to measure your blood glucose to calibrate. Do not switch your meter in the middle of a sensor session. Blood glucose meter and strip accuracy may vary between blood glucose meter brands.
- Prior to obtaining a blood glucose value to be used for calibration, wash your hands, make sure your glucose test strips are not expired and have been stored properly and that your meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with your meter or test strips.
- Make sure you are using your blood glucose meter per manufacturing instructions to ensure you are getting accurate blood glucose values for calibration.
- Make sure you have not taken any medications containing acetaminophen (paracetamol) (such as Tylenol) ingredients to ensure you are getting accurate blood glucose values for calibration.
- Clean the bottom of the transmitter with a slightly damp cloth or isopropyl alcohol wipe. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.

9.6 SENSOR SHUT-OFF TROUBLESHOOTING

In some cases your sensor session may stop or need to be stopped before the end of a full 7-day period. Once the sensor session is stopped you will need to remove your sensor.

To help improve future sensor performance:

- Make sure your sensor is not expired.
- Make sure your transmitter is fully snapped in place.
- Make sure your sensor pod is not dislodged or peeling up.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you have selected a good insertion site (see Chapter 3, Section 3.3, Choosing an Insertion Site).
- Make sure your insertion site is clean and dry prior to sensor insertion.

9.6.1. EARLY SENSOR SHUT-OFF - SENSOR FAILURE

During a sensor session the receiver may detect a series of issues with your sensor signal where it can no longer determine your glucose reading. At this time, the sensor session will end and show the screen to the right. If you see this screen it means your continuous glucose monitoring session has ended.



Press the **SELECT** button to clear this screen.

You will need to remove your sensor and insert a new sensor.

9.6.2 MANUAL SENSOR SHUT-OFF - “STOP SENSOR”

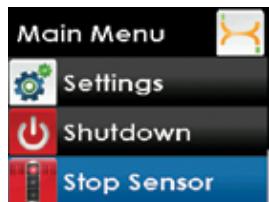
There may be times that you will want to manually stop your sensor session before the end of the seven days. Some of these times may include removing the sensor early due to:

- Calibration issues that cannot be resolved
- **???** icon that does not resolve
- Sensor adhesion issues
- Lifestyle needs

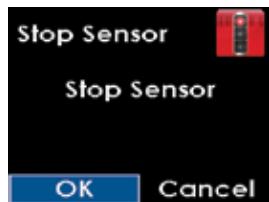
HELPFUL HINTS:

- Based on whether you are in an active sensor session, the main menu options will change.
 - When you are in an active sensor session, you will not see the “Start Sensor” option on the main menu.
 - When you are not in an active sensor session, you will not see the “Stop Sensor” option on the main menu.
- Remember to stop your sensor session if you remove your sensor before the end of the full 7 day period.

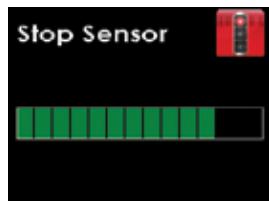
1. To manually end your sensor session, select “Stop Sensor” from the main menu.



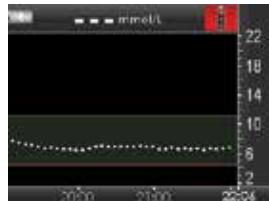
2. With “OK” highlighted, press the **SELECT** button to confirm that you want to stop the sensor session.



3. The stop sensor processing screen will appear to let you know the sensor session is stopping.



4. Once the session has stopped, a red stoplight symbol (■) will appear in the upper right corner of the trend graph.



9.7 BATTERY AND CHARGER TROUBLESHOOTING

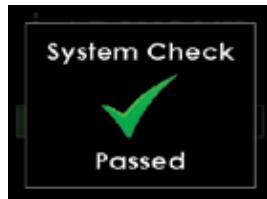
Only use the Dexcom cable and battery charger to charge your receiver.

1. Remember to charge your receiver battery as needed. The charge will last approximately 3 days, depending on how often you turn on your receiver, use the alerts, and enter events.
2. If your receiver does not show the charging icon when plugged into the charger make sure that both ends of the USB cable are fully inserted into the receiver port and wall charger.
3. If your battery drains and is not charged for a few weeks it may not turn on. If your receiver does not turn on, first try to charge it (see Chapter 1, Section 1.4, Charging Your Receiver Battery). If your receiver still does not turn on you may need to reset the receiver (connect the receiver to the charger before resetting):
 - a. Insert the end of a paperclip into the small circular hole on the back of the receiver and push down. The receiver will vibrate and show the processing screen.
 - b. You will now need to charge your receiver, and the time and date may need to be reset (see Chapter 1, Section 1.4, Charging Your Receiver Battery and Chapter 2, Section 2.2, The Settings Menu).

9.8 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

9.8.1 SYSTEM RECOVERY CHECK

This screen means that the system discovered an error that it was able to fix itself. Press the **SELECT** button to clear this display, and continue your sensor session.



9.8.2 RECEIVER ERROR CODE

This screen shows an error code and means the receiver may not be working properly. Write down the error code and contact your local distributor. Continue to check your blood glucose value using your meter.

There is no alert to warn you that you are no longer getting sensor glucose readings.



9.8.3 LOW TRANSMITTER BATTERY

This screen will appear once the transmitter nears the end of its battery life (see Chapter 1, Section 1.2, Transmitter Overview). When the transmitter battery is drained low enough the transmitter and receiver will stop communicating. Contact your local distributor to order a new transmitter.

Your transmitter battery may drain as quickly as one week after this alert appears.



9.8.4 TRANSMITTER FAILED ERROR CODE

This screen means that the transmitter is not working. If you get this alert during a sensor session, your sensor session will automatically stop. Contact your local distributor. Continue to check your blood glucose value using your blood glucose meter.



9.9 OUT OF RANGE/NO ANTENNA

This screen means your receiver and transmitter are not communicating and you are not receiving sensor glucose readings.

- Your receiver and transmitter will only communicate when you are in an active sensor session.
- Each time you start a new sensor session allow 10 minutes for your receiver and transmitter to start communicating.
- You may occasionally experience loss of communication for 10 minutes at a time. This is normal.
- If you see the out of range symbol  in the status area for more than 10 minutes, move your receiver and transmitter within 6 meters of each other. Wait 10 minutes and communication should be restored.





The transmission range from the transmitter to the receiver is up to 6 meters without obstruction. Wireless communication does not work well under water so the range is much less if you are in a pool, bathtub, water bed, etc.

- Your transmitter ID must be entered correctly into your receiver to receive sensor glucose readings (see Chapter 2, Section 2.2, The Settings Menu). Make sure you have removed your sensor and stopped your sensor session before checking or changing your transmitter ID.

HELPFUL HINT:

- You can only set your Transmitter ID when you are not in a sensor session. During a sensor session, “Transmitter ID” will not appear as an option on the Settings menu.

If you are still having trouble receiving system readings contact your local distributor.

9.10 ALERTS ARE NOT WORKING

1. Make sure you have not disabled the sound and/or vibrations for the alerts. Chapter 6, Section 6.1, Setting Your Alerts explains how to change these alert options.
2. Check to be sure you have turned on and set the level for your advanced alerts if you wish to receive these alerts (see Chapter 6, Section 6.2, Advanced Alerts).
3. Remember the first alert will vibrate only. Please see Chapter 12, Appendix I, Receiver Alerts, Alarm and Prompts sequence tables for reference on how the alerts, alarm and prompts work.

HELPFUL HINT:

- If your receiver gets wet or is dropped you need to make sure the speakers and vibrate mode are still working. You can do this by using the Try It option in the profiles menu (see Chapter 6, Section 6.3.1, Alert Profile Options).

chapter ten

TAKING CARE OF YOUR
DEXCOM G4 PLATINUM SYSTEM

10.1 MAINTENANCE

Transmitter

- Wipe the outside of the transmitter with a slightly damp cloth or isopropyl alcohol wipe between uses.
- Keep the transmitter clean and protected when not in use.

Receiver

- Do not spill fluid on the receiver or submerge the receiver in liquid.
- Keep the receiver in its carrying case or otherwise protected.
- Charge the receiver when the battery gets low.
- **Keep the micro USB port cover closed to help prevent fluid from getting inside the receiver.**

Accessories

- Insert cables only as directed. Do not force cables in place.
- Observe cables for signs of wear and tear.
- Only use Dexcom-supplied parts (including cables and chargers). Use of non-Dexcom supplied parts may affect safety and performance.

There is no repair service available for your Dexcom G4 PLATINUM CGM System. If you experience problems with your system contact your local distributor.

10.2 STORAGE

Sensor

- Keep the sensor in its sterile packaging until you are ready to use it.
- Do not insert sensors past the Use By Date. The Use By Date format is YYYY-MM-DD. Sensors must be inserted on or before the end of the calendar day printed on the sensor package label.
- Storage temperature should be 2° C - 25° C. You may store your sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.
- Store at humidity levels between 0% - 95% relative humidity.

Transmitter

- Keep the transmitter clean and protected when not in use.
- Storage temperature should be 0° C - 45° C.
- Store at humidity levels between 10% - 95% relative humidity.

Receiver

- Keep the receiver clean and protected when not in use.
- Fully charge battery before storing for over 3 months.
- Storage temperature should be 0° C - 45° C.
- Store at humidity levels between 10% - 95% relative humidity.

10.3 CLEANING AND DISINFECTION

Cleaning

DO NOT clean the power supply charger.

Cleaning removes dirt from the surface of the device. It does not kill bacteria or viruses. The receiver and transmitter should be cleaned whenever they are visibly dirty and between each use. You will need a soft, water-dampened cloth or an isopropyl alcohol wipe.

Cleaning the receiver or transmitter:

1. Close the receiver's USB port slide cover.
2. Wipe the outside of the device with a slightly damp cloth or isopropyl alcohol wipe.
3. The receiver is not waterproof. Do not use a soaking wet cloth.
4. The transmitter is water resistant when snapped into the sensor pod, but do not soak the transmitter by itself in liquid.
5. Do not use soap, nail polish remover, or paint thinner. Only use isopropyl alcohol and water.

6. For cleaning, do not use wipes that contain adhesives (e.g. Smith + Nephew IV Prep).
7. Place the device on a clean, dry cloth and air dry for 2-3 minutes.

Disinfection

Disinfection removes and destroys microorganisms and pathogens from the surface of the device. Disinfect the receiver and transmitter periodically or whenever you suspect that blood or body fluid has come in contact with the surface of the device. If a second person, such as a healthcare provider, is helping you operate the receiver or transmitter, the device should be disinfected before the second person uses it. You will need gloves, clean, dry absorbent wipes, 70% isopropyl alcohol wipes and several disinfectant wipes containing a 1:10 bleach solution (such as Alcavis Bleach Wipe 1:10 DIN 02333899, or Clorox Professional Disinfecting Bleach Wipes DIN 02349272) or sodium hypochlorite (household bleach) wipes.

Preparation:

1. Use precaution when handling products worn or handled by another person.
2. Wash hands thoroughly.
3. Wear personal protective equipment as appropriate (gloves, protective goggles, gowns, etc.).
4. Close the receiver's USB port slide cover.
5. The receiver is not waterproof. Do not use a soaking wet cloth.

Disinfecting the receiver or transmitter:

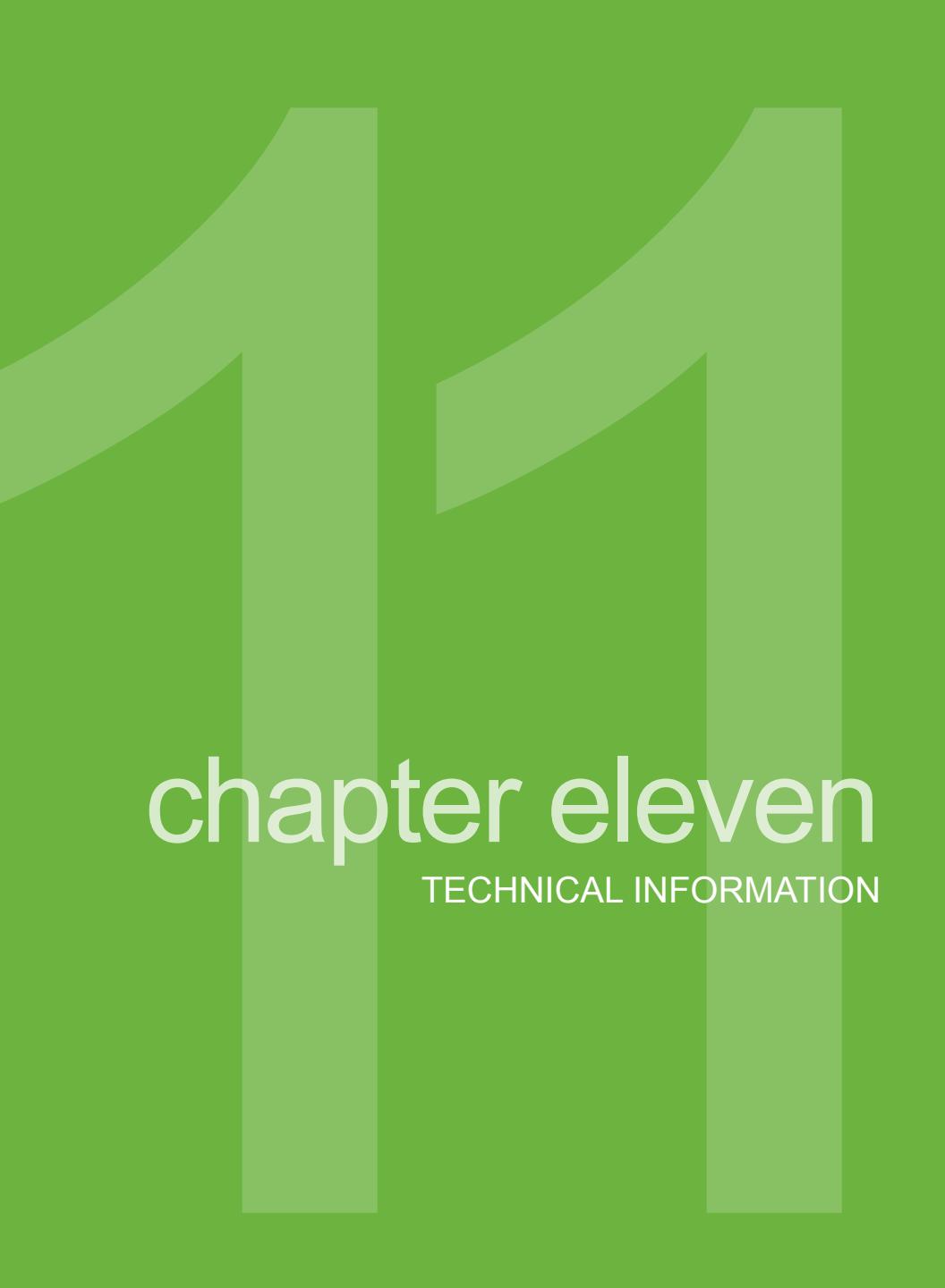
1. Wear gloves.
2. Thoroughly pre-clean the surface of any visible contamination with one disinfectant wipe (wipe the front, back and all four sides of the device).
3. Thoroughly wet the surface of the device with a second disinfectant wipe to wipe the front, back and all four sides of the device.
4. The surface should remain wet for at least 1 minute at room temperature (21° C) to ensure proper disinfection. Use additional disinfection wipes to make sure the surface stays wet for the full minute.
5. Dry the unit with a clean, dry absorbent wipe.
6. Wipe the outside of the device with a 70% isopropyl alcohol wipe to remove any disinfectant residue.
7. Dry the unit with a clean, dry absorbent wipe.

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8. Place the receiver screen side facing down on a clean, dry cloth and air dry for 60 minutes.
9. Place the transmitter on a clean, dry cloth and air dry for 2-3 minutes.
10. Remove gloves and dispose of gloves as biohazard waste.
11. Wash hands thoroughly.

10.4 PRODUCT DISPOSAL

Consult your local waste management authorities for appropriate procedures for disposal of devices containing electronic waste (transmitter and receiver) or blood contacting components (sensor and applicator).



chapter eleven

TECHNICAL INFORMATION

11.1 PRODUCT SPECIFICATIONS

Sensor

Glucose Range	2.2 – 22.2 mmol/L
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	2.2 – 22.2 mmol/L
Storage Condition	Temperature: 2° C - 25° C Humidity: 0% - 95% RH
Sterilization	Sterile by radiation

Transmitter

The Dexcom G4 PLATINUM Transmitter (Model 9438-01 and Model 9438-05) has been certified by Nemko Canada to electrical safety requirements of CSA C22.2 No. IEC 60601-1(ed. 3) and IEC 60601-1-11(ed. 1), under Certificate of Compliance **NO67180/M1**.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.



Model	9438-01	9438-05
Dimensions (including sensor pod)	Length: 3.8 cm Width: 2.3 cm Thickness: 1.3 cm	Length: 3.8 cm Width: 2.3 cm Thickness: 1.0 cm
Weight (including sensor pod)	11.3 g	8.5 g
Power Supply	Silver oxide batteries (not replaceable)	
Operational Conditions	Temperature: 10° C - 42° C Humidity: 10% - 95% RH	

Transmitter

Storage Conditions	Temperature: 0° C - 45° C Humidity: 10% - 95% RH
Operating Altitude	-152 to 3657 meters
Limited Warranty	6 months
Moisture Protection	IP28: temporary submersion
Protection Against Electrical Shock	Type BF applied part

PARAMETER	PERFORMANCE CHARACTERISTICS
TX/RX Frequencies	2.424 999 877 GHz 2.449 993 677 GHz 2.474 737 539 GHz 2.477 236 919 GHz
Bandwidth	334.7 kHz
Maximum Output Power	1.25 mW EIRP
Modulation	Minimum Shift Key
Data Rate	49.987 Kbits/Sec
Total Packet	224 bits
Transmit Duty Cycle	4.48 ms every 5 minutes at each of the four TX frequencies.
Data Detection Range	6 m

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the transmitter should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Battery operated	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Battery operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 sec	Not applicable Battery operated	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Receiver

Reading Frequency	Every 5 minutes
Dimensions	Length: 10.1 cm Width: 4.6 cm Thickness: 1.3 cm
Weight	69 g
Receiver Input	5V DC, 1A
Power Supply	MT21255
Communication Range	6 m
Memory Storage	30 days of glucose data, 7 days of tech support data
Re-Chargeable Battery Use	3 days
Charging Time	3 hours wall outlet, 5 hours powered USB
Storage/Operating Conditions	Temperature: 0° C - 45° C Humidity: 10% - 95% RH
Operating Altitude	-152 to 3657 meters
Moisture Protection	IP22: vertically falling drops
Limited Warranty	1 year
Control Classification	Class II equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver is intended for use in the electromagnetic environment specified below. The customer or the user of the receiver should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11 IEC 60601-1-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (>95% dip in U_T) for 5 sec	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G4 PLATINUM System is intended for use in the electromagnetic environment specified below. The customer or the user of the Dexcom G4 PLATINUM System should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000- 4-6 (Receiver only)	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the receiver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 1.2 \sqrt{P} \quad 150 \text{ kHz to } 80 \text{ MHz}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and television broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G4 PLATINUM System is used exceeds the applicable RF compliance level above, the Dexcom G4 PLATINUM System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G4 PLATINUM System.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Dexcom G4 PLATINUM System is intended for use in the electromagnetic environment specified below. The customer or the user of the Dexcom G4 PLATINUM System should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Dexcom G4 PLATINUM System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Dexcom G4 PLATINUM System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended below, according to the maximum output power of the communications equipment.

Rated maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Charging Cable*

Dexcom P/N	MT20655
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	0.9 m

* There is a separate AC wall charger adapter that can be connected to the USB charging/download cable for charging using an AC power outlet.

Power Supply/Charger

Dexcom P/N	MT21255
Class	II
Input:	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100Vac
DC Output:	5V DC, 1A (5.0 Watts)

11.2 DEVICE PERFORMANCE CHARACTERISTICS

NOTE:

- We recommend that you review the information in this chapter with your healthcare provider to understand how well the Dexcom G4 PLATINUM System performs.

The Dexcom G4 PLATINUM System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is “calibrated” using a commercially available blood glucose meter; and once calibrated the System reports glucose readings up to every 5 minutes. The System was evaluated in a clinical study in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, patients performed self-monitoring blood glucose meter tests at home to assess the System performance in real use environment.

Although the performance characteristics of the System are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G4 PLATINUM System.

11.2.1 SYSTEM PERFORMANCE IN ADULTS

Clinical Study Overview

The System performance was evaluated in a prospective clinical study; 72 participants were enrolled. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. About 83% of participants had Type 1 diabetes and about 17% of participants had Type 2 diabetes. The study included subjects greater than 18 years of age.

Participants used the System for seven days. Thirty-six participants each wore 2 sensors. Sensors were calibrated approximately once every 12 hours, using the self-monitoring blood glucose (SMBG) meter values obtained from the LifeScan OneTouch Ultra2 meter. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours).

All subjects were evaluated in a controlled clinic environment on Day 1, Day

4, and Day 7 of the 7-day wear period. While using the System in the clinic, participants had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the “YSI.” Readings from the System were reported every 5 minutes and paired with YSI values in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, the System performance was also paired with the comparative LifeScan OneTouch Ultra2 meter results, and that is referred to as the ‘SMBG’.

Agreement

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 20%, 30% and 40% of the YSI values. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% or 40 mg/dL (2.2 mmol/L) or 40% were then calculated in Table 1.

The total number of data pairs considered in this analysis was 9152. Of these, eighty two percent (82%) of the System readings fall within \pm 20 mg/dL (1.1 mmol/L) of the YSI blood glucose values (\leq 80 mg/dL or 4.4 mmol/L) and within \pm 20% of YSI blood glucose values ($>$ 80 mg/dL or 4.4 mmol/L).

Table 1. System Agreement to YSI within YSI Glucose Ranges

YSI Glucose Range mg/dL (mmol/L)	Number of paired CGM-YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI
Overall	9152	82%	92%	97%
40-80 (2.2-4.4)	1351	83%	94%	98%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 1 is categorized within YSI reference value ranges. When you know your blood glucose level (measured by YSI in the study), this table shows how likely your CGM reading matches with your blood glucose level. For example when your blood glucose level is less than 80 mg/dL (4.4 mmol/L), you can expect your CGM reading to be within 20 mg/dL (1.1 mmol/L) of YSI values, i.e. 60 to 100 mg/dL (3.4-5.6 mmol/L), 83% of the time.

Accuracy

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL (5.6 mmol/L) and the System reading is 90 mg/dL (5.0 mmol/L), a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected. In the example above, the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI at each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between System readings and YSI values.

These accuracy measures in differences are based on 9152 paired glucose results and summarized in the following Table 2.

Overall, the System reads, on average, 13.3% absolute different (Mean Absolute Difference) than the reference values. The Median Absolute Percent Difference shows that half of the time the System reads about 9.8% or less different than YSI blood glucose values. The mean percent difference overall is 2.9%, and the median percent difference overall is 1.7%. This shows that the system is biased slightly higher than compared to the YSI.

Table 2. System Difference to YSI within YSI Glucose Ranges

YSI Glucose Ranges mg/dL (mmol/L)	Number of Paired System-YSI	Mean Absolute Difference	Median Absolute Difference
Overall	9152	13.3%	9.8%
40-80 (2.2-4.4)	1351	11.8 mg/dL (0.66 mmol/L)	9.6 mg/dL (0.53 mmol/L)

*For YSI less than 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels (concentrations) is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI readings were compared by pairing the System reading that occurred immediately after the YSI reading was collected. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Tables 3-A and 3-B.

Table 3-A. Hypoglycemic Alert Evaluation – 15 Minutes Before and After

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	50%	50%	71%	29%
60 (3.3)	64%	36%	75%	25%
70 (3.9)	79%	21%	83%	17%
80 (4.4)	87%	13%	86%	14%
90 (5.0)	90%	10%	89%	11%
100 (5.6)	93%	7%	90%	10%

Table 3-B. Hypoglycemic Alert Evaluation – 30 Minutes Before and After

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	62%	38%	75%	25%
60 (3.3)	74%	26%	79%	21%
70 (3.9)	86%	14%	87%	13%
80 (4.4)	93%	7%	90%	10%
90 (5.0)	94%	6%	92%	8%
100 (5.6)	96%	4%	93%	7%

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed (Table 3-A) or within 30 minutes before or after the device alarmed (Table 3-B). The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 or 30 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL (3.9 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be low? If your alarm sounds, you can expect your blood sugar to be below 70 mg/dL (3.9 mmol/L) approximately 86% of the time and not be below 70 mg/dL (3.9 mmol/L) approximately 14 % of the time within the 30 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 minutes before or after the blood glucose was at or below the alert settings (Table 3-A) or within 30 minutes before or after the blood glucose was at or below the alert settings (Table 3-B). The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 or 30 minutes before or after the blood glucose was at or below the alert setting.

Methodology for the Hypoglycemia Detection Rate includes if the sensor glucose value is at or below the low alert level 15 or 30 minutes before and 15 or 30 minutes after the actual low glucose event. This does not include any predictive alert contribution.

For example, if you set the Low Glucose alert to 70 mg/dL (3.9 mmol/L), how often will your alarm alert you if your blood glucose goes below 70 mg/dL (3.9 mmol/L)? If your blood sugar goes below 70 mg/dL (3.9 mmol/L), you can expect your alarm to sound 87% of the time and not to sound approximately 13% of the time within the 30 minute period before or after your blood sugar goes below 70 mg/dL (3.9 mmol/L).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 4.

Table 4. Hyperglycemic Alert Evaluation

Hyperglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120 (6.7)	95%	5%	98%	2%
140 (7.8)	94%	6%	97%	3%
180 (10.0)	92%	8%	97%	3%
200 (11.1)	92%	8%	97%	3%
220 (12.2)	91%	9%	95%	5%
240 (13.3)	91%	9%	94%	6%
300 (16.7)	82%	18%	86%	14%

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL (11.1 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be high? If your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL (11.1 mmol/L) approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set the High Glucose alert to 200 mg/dL (11.1 mmol/L), how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL (11.1 mmol/L)? If your blood sugar goes above 200 mg/dL (11.1 mmol/L), you can expect your alarm to sound 97% of the time and not to sound approximately 3% of the time within the 15 minute period before or after your blood sugar goes above 200 mg/dL (11.1 mmol/L).

Sensor Stability

Sensors can be worn for up to 7 days. To verify sensor performance over time, 108 sensors were evaluated across the 7-day wear period. Performance was estimated by calculating the percentage of System readings within 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% or 40 mg/dL (2.2 mmol/L) of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 5 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Table 5. Sensor Stability (Accuracy over Time)

Day of Wear	Number of Paired CGM-YSI	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 20/20% YSI*	Percent within 30/30% YSI*	Percent within 40/40% YSI*
Day 1	3023	16.7%	13.2%	71%	86%	94%
Day 4	3108	11.4%	8.2%	87%	95%	98%
Day 7	3021	11.9%	8.9%	87%	95%	98%

Precision of System Readings

In the study, 36 participants wore two Systems. This was to look at how similarly two Systems function on the same patient (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, 108 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (4%) sensors that ended early, four of which lasted more than 3 days.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Adjusted within each system wear-day, the System provided an average of 97% of all expected glucose readings (288).

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results. The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance patients expect during real-time use of the system in their daily diabetes management when comparing the system readings to their home blood glucose meter results.

Table 6. System Agreement to SMBG within CGM Glucose Ranges

CGM Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent within 40/40% SMBG
40-400 (2.2-22.2)	7508	81%	94%	98%
40-80 (2.2-4.4)	1699	85%	94%	97%

Table 6 is categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% or 40 mg/dL (2.2 mmol/L) or 40% were then calculated.

Table 7. System Difference to SMBG within CGM Glucose Ranges

CGM Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-SMBG	Mean Absolute Difference	Median Absolute Difference
40-400 (2.2-22.2)	7508	14.0%	11.0%
40-80 (2.2-4.4)	1699	11.2 mg/dL (0.62 mmol/L)	8.0 mg/dL (0.44 mmol/L)

Overall, the System reads, on average, 14.0% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median Absolute Percent Difference shows that half of the time the System reads about 11.0% or less different than SMBG values (Table 7).

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the study. Mild skin irritation, such as erythema or edema, occurred in low frequency around adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

11.2.2 SYSTEM PERFORMANCE IN PEDIATRICS

Clinical Study Overview

The System performance was evaluated in a prospective clinical study, 30 participants were enrolled. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin to manage their diabetes. About 97% of participants had Type 1 diabetes and about 3% had Type 2 diabetes. The average age of study subjects was 12 years old, the youngest subject was 2 years of age and the oldest subject was 17 years of age.

Participants used the System for seven days; each participant wore 2 sensors. Sensors were calibrated approximately once every 12 hours, using the SMBG values obtained from the Lifescan® OneTouch® Verio™ IQ meter. Throughout the 7-day wear period, the Sensor was calibrated with an average of 2 fingersticks per day. The study took place at home, the System performance was also paired with the comparative meter results, and that is referred to as the reference 'SMBG'.

Agreement

Agreement between the System and blood glucose values is characterized using paired sensor and SMBG values. The sensor and SMBG results were compared by pairing the SMBG to a sensor glucose reading that occurred immediately after the SMBG was collected within 5 minutes. These results present the performance patients expect during real time use of the system in their daily diabetes management when comparing the system readings to their home blood glucose meter results.

The agreement of the sensor to reference glucose value was assessed by calculating the percentage of sensor readings that were within 20%, 30%, and greater than 40% of the SMBG values. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, or within 40 mg/dL (2.2 mmol/L) or 40%, within glucose measurable ranges were then calculated (Table 1).

The total number of data pairs considered in this analysis was 1882. Of these, seventy-seven percent (77%) of the sensor readings fall within 20 mg/dL (1.1 mmol/L) of the SMBG glucose values (≤ 80 mg/dL, i.e. 4.4 mmol/L) and within 20% of SMBG glucose values (>80 mg/dL, i.e. 4.4 mmol/L).

Table 1. Percentage of CGM Readings Within SMBG Values

Glucose Ranges mg/dL (mmol/L)	Number of Matched Pairs (n)	Percent within 20/20	Percent within 30/30	Percent within 40/40
40-400 (2.2-22.2)	1882	77%	90%	95%

Accuracy

Accuracy between matched pairs was also estimated by calculating the percent difference between the sensor reading and the SMBG value. For example, if the reference value is 100 mg/dL (5.6 mmol/L) and the sensor reading is 90 mg/dL (5.0 mmol/L), a 10% difference between the sensor and the SMBG value is reported.

In the example above the sensor reading is less than the SMBG value, so the percent difference reading is negative. The absolute percent difference tells you the relative difference in percentage or “relative distance” between the sensor and SMBG values. The average and median of the differences are summarized and are based on 1882 paired glucose results at different glucose ranges (Table 2).

Table 2. System Difference to YSI within YSI Glucose Ranges

Glucose Ranges mg/dL (mmol/L)	Number of Matched Pairs (n)	Mean Absolute Difference	Median Absolute Difference
40-80 (2.2-4.4)	1882	14.9%	11.6%

Overall, the System reads, on average, 14.9% absolute different (Mean Absolute Percent Difference) than SMBG values at glucose levels of 40-400 mg/dL (2.2-22.2 mmol/L). The Median Absolute Percent Difference shows that 50% of the time the System reads about 11.6% or less different than the reference glucose values.

Sensor Stability

Sensors can be worn for up to 7 days. To verify sensor performance over time, 108 sensors were evaluated across the 7-day wear period. Performance was estimated by calculating the percentage of System readings within 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% or 40 mg/dL (2.2 mmol/L) of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 5 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Table 3. System Sensor Stability (Accuracy over Time)

Day of Wear	Number of Matched Pairs (n)	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 20/20	Percent within 30/30	Percent within 40/40
Day 1	311	18.1%	13.0%	69%	82%	88%
Day 2	300	16.2%	12.8%	74%	88%	95%
Day 3	302	14.2%	11.7%	79%	92%	99%
Day 4	273	14.9%	10.9%	75%	90%	94%
Day 5	275	13.5%	10.8%	82%	93%	97%
Day 6	201	13.0%	10.3%	84%	96%	98%
Day 7	220	12.9%	10.5%	82%	94%	96%

Precision of System Readings

In the same study, all subjects wore two Systems. This was to look at how well sensors agree with each other when use by the same person. Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that System readings from the two sensors generally agreed with each other within 8% (absolute percent difference) and had a 6% coefficient of variation.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, 59 sensors were evaluated to determine how many days/hours of readings each sensor provided. Eighty-one percent (81%) of the sensors lasted until Day 7 (145-168 hours).

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Adjusted within each system wear-day, the System provided an average of 92% of all expected glucose readings (288).

Adverse Events

There were two adverse events identified as skin irritations (erythema), reported from one subject at the sensor patch adhesive area. No device-related serious adverse events occurred during the study. No noticeable infection, bruising, or bleeding occurred at the sensor needle insertion area and the patch adhesive area.

11.3 FCC REQUIREMENTS

The transmitter covered by this user's guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

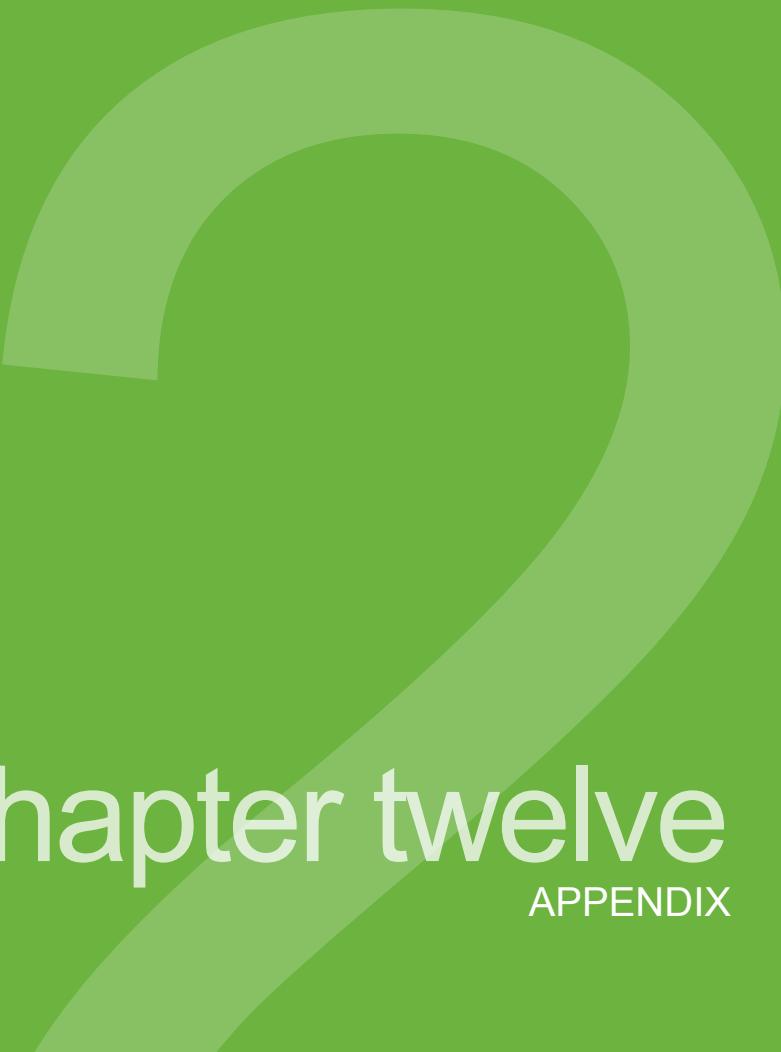
FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.



chapter twelve

APPENDIX

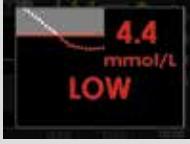
APPENDIX I, RECEIVER ALERTS, ALARM AND PROMPTS

The following tables describe the alarm, alerts and prompts and how the receiver notifies you.

Prompt - Shows on screen only. Silent, no vibrate or beep.

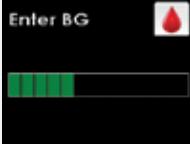
Alert - Notifies with vibrate and beep depending on your profile settings.

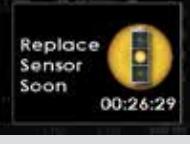
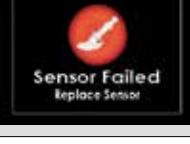
Alarm - Low 3.1 - Notifies with vibrate and beep. Cannot be changed.

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Low glucose alert	Your most recent sensor glucose reading is at or below 3.1 mmol/L.	Vibrates 4 times, then vibrates/beeps 4 times every five minutes until confirmed or your glucose value goes above 3.1 mmol/L.	Yes, every 30 minutes after each confirmation) until your blood glucose value comes back into range.
	High glucose alert	Your most recent sensor glucose reading is at or above the high alert setting.	Vibrates twice, then vibrates/beeps twice every 5 minutes until confirmed or your glucose value drops below the alert level.	No, unless you have turned on the high snooze feature. See Chapter 6.2, Advanced Alerts.
	Low glucose alert	Your most recent sensor glucose reading is at or below the low alert setting.	Vibrates three times then vibrates/beeps three times every 5 minutes until confirmed or your glucose value goes above the alert level.	No, unless you have turned on the low snooze feature. See Chapter 6.2, Advanced Alerts.
	Low battery alert	The receiver battery is low. Charge your receiver as soon as possible when you see this alert.	Vibrates once at 20% battery capacity left.	Yes, at 10% battery capacity left.

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
 Out of Range for 00:20:26	Out of range alert	The transmitter and receiver are not communicating and you will not receive sensor glucose readings.	1 vibrate then vibrate/beep every 5 minutes until the receiver and transmitter are back in range.	No unless you have turned on the out of range alert.
	Unknown sensor prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
	Wait prompt	The receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values during this time. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
 Enter BG in 15min	15 minute calibration error alert	The sensor cannot calibrate. Wait 15 minutes then enter 1 more blood glucose value. Wait 15 more minutes. If error screen still appears enter 1 more blood glucose value. Wait 15 minutes. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	No

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	1 hour calibration error alert	The sensor cannot calibrate. Wait a minimum of 1 hour then enter 1 more blood glucose value for calibration. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	No
	12 hour calibration prompt	The receiver needs a blood glucose value entered to calibrate.	Prompt screen only.	Yes, every 15 minutes.
	Additional calibration prompt	The receiver needs a blood glucose value entered to calibrate. Sensor glucose readings will not be displayed at this time.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	Yes, every 15 minutes.
	Startup calibration prompt	The receiver needs 2 blood glucose values entered to calibrate.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	Yes, every 15 minutes.
	Additional startup calibration prompt	The receiver needs 1 additional blood glucose value to complete startup calibration.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	Yes, every 15 minutes.

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	Enter BG processing screen prompt	The receiver is processing the blood glucose value you entered.	Prompt screen only.	N/A
	Rise alert	Your glucose levels are rising at 0.11 mmol/L per minute or more.	2 vibrates then 2 vibrates/2 beeps every 5 minutes (2 times) or until confirmed.	No
	Rapid rise alert	Your glucose levels are rising fast at 0.17 mmol/L per minute or more.	2 vibrates then 2 vibrates/2 beeps every 5 minutes (2 times) or until confirmed.	No
	Fall alert	Your glucose levels are falling at 0.11 mmol/L per minute or more.	3 vibrates then 3 vibrates/3 beeps every 5 minutes (2 times) or until confirmed.	No
	Rapid fall alert	Your glucose levels are falling fast at 0.17 mmol/L per minute or more.	3 vibrates then 3 vibrates/3 beeps every 5 minutes (2 times) or until confirmed.	No

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
	6-hour sensor expiration prompt	Your sensor session will end in 6 hours.	Prompt screen only.	N/A
	2-hour sensor expiration prompt	Your sensor session will end in 2 hours.	Prompt screen only.	N/A
	30-minute sensor expiration alert	Your sensor session will end in 30 minutes.	1 vibrate then vibrate/beep every 5 minutes (2 times).	No
	End of session sensor expiration alert	Your sensor session has ended.	1 vibrate then vibrate/beep every 5 minutes (2 times).	No
	Sensor failed alert	The sensor is not working properly.	1 vibrate then vibrate/beep every 5 minutes (2 times).	Yes, 2 re-alerts in the next 10 minutes for 30 minutes.

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
 Call local Distributor Error E00117	Receiver error alert	Your receiver is not working properly. Record the error code and call your local distributor.	1 vibrate (4 seconds) + 4 beeps.	No
	System check alert	There was a system error and the receiver fixed it.	1 vibrate then vibrate/beep every 5 minutes until confirmed.	No
	Set time/date prompt	Backup battery has drained, time/date need to be reset.	1 vibrate	No
	Transmitter low battery alert	Transmitter battery is low. Replace the transmitter as soon as possible.	1 vibrate then vibrate/beep every 5 minutes (2 times).	Yes, once a day.
	Transmitter failed alert	The transmitter has failed. Replace the transmitter immediately.	1 vibrate then vibrate/beep every 5 minutes (2 times).	No

Important alerts and alarms that can be verified by the user:

- **Out of Range Alert** - You can test this alert by moving the receiver more than 6 meters away for 30 minutes or more.
- **30-minute sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.
- **0-hour sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.

Other alerts and alarms cannot be safely verified by the user.

GLOSSARY

Alternative Site BG Testing	This is when you obtain a blood glucose value on your meter using a blood sample from an area on your body other than your fingertip. Do not use alternative site testing for entering blood glucose values into the receiver.
Applicator	A disposable component piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator barrel that you remove once you have inserted the sensor.
BG Meter	Blood glucose meter. You can use any commercially available meter for obtaining blood glucose values to enter into your receiver.
BG Value	Blood glucose value. A blood glucose value taken with your commercially available blood glucose meter.
Calibration	This is when you enter blood glucose values from a blood glucose meter into the receiver. Calibrations are needed for your receiver to display continuous sensor glucose readings and trend information. (Do not use alternative site testing for calibration.)
CGM	Continuous Glucose Monitoring
Default	A setting that is selected automatically unless another option is chosen.
Dexcom G4 PLATINUM System	The sensor, transmitter, and receiver.
Glucose Data Gaps	This can happen when the receiver does not display a glucose reading that is sent from the transmitter. A symbol will appear instead of a glucose reading to let you know that the receiver cannot display a reading.
Glucose Trends	Trends let you see the pattern of your glucose levels; you can see where your glucose levels have been and where your glucose levels are. The graph shows glucose trends over the amount of time shown on the screen.
mmol/L	Millimoles per liter. The international standard unit of measuring blood glucose levels.
Profiles	Sound pattern and volume level settings for your alerts.

GLOSSARY (continued)

Range	The distance between the receiver and transmitter. Keep the two devices within 6 meters from each other to get glucose information on your receiver.
Re-alert	A re-alert occurs when the initial alert has not been confirmed.
Receiver	The small device which collects your glucose information from the sensor/transmitter. Your results are displayed on the receiver screen as a sensor glucose reading (mmol/L) and as a trend.
Rise and Fall (Rate of Change) Alerts	Alerts based on how fast your glucose levels rise/fall, and by how much.
RF	Radio-frequency transmission used to send glucose information from the transmitter to the receiver.
Safety Lock	The safety lock keeps the needle inside the applicator before you are ready to insert the sensor. It also helps you snap the transmitter out of the sensor pod after your sensor session has ended.
Sensor	The part of the sensor that is inserted under your skin with the applicator. It measures the glucose levels in your surrounding tissue fluid.
Sensor Pod	The small plastic base of the Sensor attached to your belly that holds the transmitter in place.
Snoozing	A snooze time (every 15 minutes up to 5 hours) can be set in between high and low glucose re-alerts.
Startup Period	The 2-hour "startup" period after you tell the receiver you have inserted a new sensor (sensor glucose readings are not provided during this time).
System Reading	A sensor glucose reading shown on your receiver. This reading is given in mmol/L units and is updated every 5 minutes.
Transmitter	The Dexcom G4 PLATINUM System component that snaps into the sensor pod and wirelessly sends glucose information to your receiver.
Transmitter ID	Transmitter ID that is entered into your receiver to enable it to communicate with the transmitter.

GLOSSARY (continued)

Transmitter Latch	The small disposable component that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in place.
Trend (Rate of Change) Arrows	Arrows on trend graphs that indicate if and how fast your glucose levels are changing. There are 7 different arrows that show when your glucose speed and direction change.

SYMBOLS USED IN LABELING

The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G4 PLATINUM CGM System. Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

	“Use By” Date		Lot Number
	Caution		Part Number, Catalog Number
	Date of Manufacture		Sterile by Radiation
	Do Not Reuse		Two-sided Temperature Limits
	Serial Number		Temporary submersion
	Class II Equipment		Vertically falling drops
	Alternating Current		Direct Current

	Type BF Applied Part		Follow Operating Instructions
	Manufacturer		Authorized Representative in the European Community
	Two-Sided Humidity Limitation		Non-ionizing Radiation
	European Union WEEE Directive 2006-66-EC		Marking Certifies that the device meets the European Council Directive 93/42/EEC
	Electrical Equipment Designed Primarily for Indoor Use		Do Not Use if Package is Damaged
	Input		Ship By Date
	Keep Dry		Marking Certifies that the device meets the CSA-C22.2 No. IEC 60601-1(ed.3) and IEC 60601-1-11(ed. 1) Standard

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